The development of a psychological intervention to optimise insulin initiation in type 2 diabetes

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The development of a psychological intervention to optimise insulin initiation in type 2 diabetes

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Abstract

Background:

Type 2 diabetes is a progressive condition where beta cell function deteriorates over time. Insulin injection therapy is often required 5-10 years post-diagnosis, but many people who require insulin delay starting it. There are currently education groups available for people with type 2 diabetes starting insulin, but these have been designed to support safe insulin administration and do not consider psychological problems or barriers, such as fear of hypoglycaemia or weight gain. There is evidence to support the effectiveness of group education and psychological interventions for people with type 2 diabetes, but so far insulin group education has not been evaluated. Research is needed to develop psychologically informed insulin group education which incorporates elements of psychological interventions for people with type 2 diabetes, to understand how psychological factors such as depressive symptoms, diabetes distress and insulin beliefs affect initiation of insulin and to understand from people who have attended insulin education their views of it and how it could be improved.

Methods:

Study 1 is a systematic review and meta-analysis to assess the effectiveness of behaviour change techniques in psychological interventions to improve HbA1c for people with type 2 diabetes. Study 2 used qualitative semi-structured interviews to determine the views of people with type 2 diabetes in south London who had attended insulin education, regarding barriers to insulin self-management, views on current insulin group education, and suggestions for additional support to aid insulin self-management. Study 3 is an 8-year medical records follow-up of an existing National Institute of Health Research funded south London Diabetes cohort (SOUL-D) of n=1735 people with type 2 diabetes. It examined whether psychological factors (depressive symptoms, diabetes distress and insulin beliefs) around diagnosis delay time to insulin initiation and insulin requiring status in people with type 2 diabetes. Finally, study 4 combined evidence from studies 1-3 to inform the manual development of a psychological intervention called Diabetes Insulin Management Education (DIME). The DIME intervention aimed to optimise insulin initiation in people with type 2 diabetes. Initial testing of DIME took place with groups of people with type 2 diabetes who initiated insulin (from south London). Study 5 was a qualitative (one-to-on exit interviews) and quantitative (case study of interviewees) evaluation of the DIME pilot sessions to determine acceptability (study 5).

Results:

In study 1, the most commonly used behaviour change techniques in psychological interventions which were associated with improved HbA1c included 'social support', 'feedback and monitoring', and 'goal setting'. Study 2 revealed positive experiences of insulin group education for people with type 2 diabetes was linked to sharing experiences with other people starting insulin, reassurance from healthcare professionals, appropriate supportive materials, and skill of the facilitator to address insulin concerns and manage group dynamics. In study 3, in a cox regression, depressive symptoms at type 2 diabetes diagnosis (HR=1.06, 95% CI=1.02-1.10, p=0.005) were the only psychological factor which predicted significantly shorter time insulin initiation, controlling for other baseline confounding variables. Following initial testing of DIME, positive feedback included: alleviation of fears and anxieties around insulin; positive communication style; finding common ground with people in the group; and group dynamics were managed well.

Conclusions:

Psychological interventions as well as behaviour change technique categories are beneficial to improving HbA1c. A group environment and facilitator skill play a key role in positive impact of insulin education. Appropriate psychological techniques to address depressive symptoms should be taken into consideration in development of insulin initiation education. Initial testing of a psychological intervention to optimise insulin initiation provides positive feedback and improvement in HbA1c and should be tested in a randomised controlled trial to determine effectiveness.

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List of publications

Peer-reviewed publications included in thesis

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Other peer-reviewed publications

Winkley, K., **Upsher, R.,** Polonsky, W., Holmes-Truscott, E. (in press). The psychosocial aspects and contributions of behavioural science to medication-taking for adults with type 2 diabetes. *Diabetic Medicine.*

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Bradbury, D*., **Upsher, R***., & Chilcot, J. (2018). A pilot randomised test of a self-affirmation implementation intention intervention to reduce dietary salt intake. *Journal of health psychology*, *23*(6), 765-775. *D.B. and R.U. are joint first authors

Conference abstracts

Upsher, R., Lake, L., Forbes, A., Chamley, M., Ismail, K., & Winkley, K. (2019). The association between depressive symptoms and time to initiating insulin in people with Type 2 diabetes. *Diabetic medicine, 36* (S1), 150-154. (oral presentation)

Upsher, R., Allen-Taylor, M., Reece, I., Chamley, M., Ismail, K., Forbes, A., & Winkley, K. (2018) A qualitative study to determine the experiences of people with Type 2 diabetes starting insulin in south London and their views of education received. *Diabetic medicine, 35* (S1), 112-135. (poster presentation)

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Under review

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The work presented in this thesis was undertaken as part of independent research funded by the United Kingdom's National Institute for Health Research (NIHR) under its Individual Award Programme (Reference Number: ICA-SCL-2015-01-002) in addition to being supported by the National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research and Care south London at King's College Hospital NHS Foundation Trust. The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health.

To the best of my knowledge, the work presented in this thesis is original and my own work, except where acknowledged in the text.

This thesis has not been submitted for any other degree at any other university.

Reflexivity statement

What is reflexivity?

Reflexivity refers to minimising bias that results from researchers' prior knowledge, experience and assumptions that can influence the research process at any stage.

A strength of this thesis is the reflexive research design in including a multidisciplinary research team to allow for a broad understanding of the topic from design, analysis and interpretation of findings.

Reflexivity can involve including researchers of different expertise; reporting research process in detail; and reporting background of researchers and role in research for transparency.

This statement details reflexive processes which occurred in this thesis.

Prior assumptions and experiences

This thesis contains 5 different studies: study 1 (meta-analysis); study 2 (qualitative analysis); study 3 (prospective cohort study); study 4 (development of a psychological intervention); study 5 (qualitative and quantitative evaluation of pilot sessions of the psychological intervention).

To reflect on my own personal background, I have been involved with type 2 diabetes research since 2015 during my MSc Health Psychology placement with Dr Kirsty Winkley in the Diabetes, Psychiatry, and Psychology research group. Following my master's degree, I worked as a research assistant before enrolling on the PhD programme within the same research group at King's College London. It should also be noted I have type 1 diabetes (since 2010) which could have influenced my perspective on diabetes self-management behaviours and experience of living with diabetes.

To overcome potential bias of my own background, other researchers of varying disciplines have been involved with different stages of this thesis. The following table displays the name of researchers involved in the different studies of this thesis, their background, and their role in this research process.

Name	Study of thesis involved with	Background	Role in research process
Dr Kirsty Winkley	ALL	Reader in Diabetes and Primary Care; Diabetes Nurse; Health Psychologist	1st PhD Supervisor Study 1- screening of papers, data extraction, interpretation of results. Study 2- development of topic guide, qualitative data collection, assessment of information power, qualitative data analysis support; interpretation of qualitative results. Study 3- data analysis plan, quantitative data collection support, interpretation of quantitative results. Study 4- defining and selecting target behaviour(s); evaluating intervention functions, policy categories and behaviour change techniques; psychological intervention pilot facilitator, modifications of psychological intervention manual. Study 5- development of topic guide, qualitative data analysis support; interpretation of qualitative results.
Professor Khalida Ismail	ALL	Professor of Psychiatry & Medicine	2nd PhD Supervisor Study 1- coding of psychological interventions, interpretation of results. Study 2- interpretation of qualitative results. Study 3- data analysis plan, quantitative data collection support, interpretation of quantitative results. Study 4-plan of psychological intervention development, review of psychological intervention development. Study 5- interpretation of qualitative results.
Professor Daniel Stahl	Study 1 Study 3	Professor of Medical Statistics & Statistical Learning	Statistical analysis support; interpretation of quantitative results.
Maya Allen-Taylor	Study 2	Diabetes Nurse	Qualitative data collection and analysis.
Ilse Reece	Study 2	Diabetes Nurse	Interpretation of qualitative results.
Dr Mark Chamley	Study 2	General Practitioner-Diabetes clinical lead	Interpretation of qualitative results.

Professor Angus Forbes	Study 2	Professor & Chair of Clinical Diabetes Nursing	Qualitative data analysis support; interpretation of qualitative results.
Deborah Onabajo	Study 2	MSc Health Psychology student; trained in behaviour change technique taxonomy	Coding behaviour change techniques from psychological intervention descriptions; interpretation of results.
Anne Sophie Mathiesen	Study 5	Diabetes nurse, PhD student in health and medical sciences	Qualitative data analysis.

Data collection of qualitative interviews

Qualitative interviews in study 2 were conducted at the participants' local general practice surgery. Qualitative interviews in study 5 were conducted immediately after the 3rd session of the pilot psychological intervention which took place at a local general practice surgery or community venue. For both studies these venues were chosen for convenience and to maximise recruitment. Interviewers were not the participants healthcare professionals; therefore, researchers hoped the participants would feel comfortable sharing their views within the healthcare setting.

Before the interviews commenced in study 2 and 5, interviewers introduced themselves i.e. who they worked/studied for (King's College London) and provided information regarding the research. Diabetes nurses who were involved with data collection did not interview any of their patients. It was emphasised the discussion was to gain views on their experience of the insulin education groups so future developments could be made. For study 2, I did not disclose that I had type 1 diabetes to the participants as I was more interested in their experience as opposed to comparing experiences. In study 5, I revealed I had type 1 diabetes during the pilot sessions of the new psychological intervention (study 4), where participants described feeling reassured to hear from someone else with diabetes who was treated with insulin. Regardless of this disclosure, in study 5, interviewees openly discussed their feedback of the psychological intervention. During study 2, sometimes the participants did ask diabetes medical questions, they were politely asked to seek advice from their diabetes nurse or general practitioner as to not conflict with the aims of the research. In addition, for the interviews I conducted it was not appropriate for me to offer medical advice as I am not a medical professional. Though I felt none of the medical questions were of great concern and did not compromise the safety of the participant, I did report these concerns to members of the research team who were diabetes nurses (KW & MA) and responsible for their care.

Even though I could empathise with some of the experiences of living with diabetes, I refrained from commenting on these as to not influence the interviewees responses to interview questions. It was only appropriate to reflect on my own personal experience when asked by the group in the psychological intervention pilot sessions.

Data analysis of qualitative research

Field notes were made by all interviewers and were made immediately after interviews occurred. These were useful to refer to when analysing data and discussing themes between researchers for detailed interpretation of data. There were multiple interviewers for study 2 so each researcher listened to audiotapes of interviews conducted by the other 2 researchers to identify any interviewer bias to be eliminated in subsequent interviews. Final themes were generated after discussions within the wider research team to reduce bias in interpretation of results.

Reporting of qualitative research

Qualitative research bias was reduced by reporting a range of perspectives, so the viewpoint of one group is not represented as the sole truth (known as 'fair dealing'). In study 2, people with type 2 diabetes were purposively sampled by sex, age (</45, 46-59, 60+ years), and ethnicity (White, Black, south Asian/other) to obtain views from a range of people. This was not possible in study 5 as there were only 3 participants who attended all three sessions of the psychological intervention. The aim of qualitative analysis was to identify common themes that emerged across participants. In addition, quotes were reported relating to specific individual accounts with the aim of reporting views of individuals as well as the majority.

Awareness of wider context from results of qualitative research

In study 2, the concept of 'transferability' is discussed whereby the results of the qualitative analysis can be applied to another sociocultural setting. Study 2's results can be applied to existing theoretical health models which were then used to develop the new psychological intervention in study 4.

Improving reflexivity in the future

This thesis took steps to reduce bias across all 5 studies. To reduce bias in the future, people with type 2 diabetes could be involved with further development of the psychological intervention to offer further perspectives of the work to assist application to real-life healthcare settings.

Abbreviations

Author name abbreviations referred to in thesis: Rebecca Upsher (RU), Kirsty Winkley (KW), Khalida Ismail (KI), Daniel Stahl (DS), Deborah Onabajo (DO), Maya Allen-Taylor (MA), Anne Sophie Mathiesen (ASM).

ACCORD	Action to Control Cardiovascular Risk in Type 2 Diabetes
ACR	Albumin to Creatinine Ratio
ADA	American Diabetes Association
ADVANCE	Action in Diabetes and Vascular Disease Preterax and Diamicron MR Controlled Evaluation
APEASE	Affordability, Practicability, Effectiveness and cost-effectiveness, Acceptability, Side effects and safety, Equity
BCTTv1	Behaviour Change Technique Taxonomy v1
BECCI	Behaviour Change Counselling Index
BIT	Barriers to Insulin Treatment
CBT	Cognitive Behavioural Therapy
CI	Confidence Interval
CINAHL	Cumulative Index to Nursing and Allied Health Literature
COM-B	Capability, Opportunity, Motivation- Behaviour
COREQ	Consolidated Criteria for REporting Qualitative research checklist
DARN-CAT	Desire Ability Reason Need- Commitment Activation Taking Steps
DCCT	Diabetes Control and Complications Trial
DECS	Diabetic Eye Complications Screening
DESMOND	Diabetes Education and Self-Management for Ongoing and Newly Diagnosed
DIME	Diabetes Insulin Management Education
DPP-4	Dipeptidyl peptidase-4
DSMES	Diabetes Self-Management Education and Support
DUK	Diabetes UK
D-6	Diabetes-6
EASD	European Association for the Study of Diabetes
EDS	Edinburgh Depression Scale
eGFR	estimated Glomerular Filtration Rate

E-P-E	Elicit-Provide-Elicit
EMIS	Egton Medical Information Systems
GLP-1 RAs	Glucagon-Like Peptide-1 Receptor Agonists
HADS	Hospital Anxiety and Depression Scale
HbA1c	Glycated haemoglobin
HR	Hazard Ratio
ID	Identification
IDF	International Diabetes Federation
IRAS	Integrated Research Application System
ITAS	Insulin Treatment Appraisal Scale
KDA	Korean Diabetes Association
MeSH	Medical Subject Headings
mITAS	modified Insulin Treatment Appraisal Scale
MITI	Motivational Interviewing Treatment Integrity
MOVE-IT	The MOtiVational interviewing InTervention
MRC	Medical research council
NHS	National Health Service
NICE	The National Institute for Health and Care Excellence
NPH	Neutral Protamine Hagedorn
OAD	Oral AntiDiabetic medications
OARS	Open ended questions, Affirmations, Reflective listening, Summarising
PAID	Problem Areas In Diabetes
PCSE	Primary Care Support England
PHQ-9	Patient Health Questionnaire- 9 item
PPI	Public Patient Involvement
PRISMA	Preferred Reporting Items for Systematic reviews and Meta-Analyses
PROSPERO	Prospective Register of Systematic Reviews
SD	Standard Deviation
SIGN	Scottish Intercollegiate Guidelines Network
SMD	Standardised Mean Difference
SOUL-D	SOuth London-Diabetes
TIDieR	Template for Intervention Description and Replication

UKPDS	UK Prospective Diabetes Study
WHO	World Health Organization

Chapter 1 : *Introduction*

1.1. Definition of type 2 diabetes and epidemiology

Type 2 diabetes is a progressive condition characterised by hyperglycaemia (high blood glucose levels). Hyperglycaemia in type 2 diabetes is caused by insulin resistance and beta cell dysfunction (DeFronzo, 2004). Type 2 diabetes develops as insulin resistance rises and then beta cells compensate by secreting more insulin to normalise blood glucose. Over time beta cell function deteriorates, less insulin is secreted, and blood glucose levels rise. At diagnosis people with type 2 diabetes have impaired glucose tolerance, impaired fasting glucose and hyperglycaemia (DeFronzo, 2004), figure 1.1. Development of type 2 diabetes is associated with diabetes complications (Stratton et al., 2000). Type 2 diabetes can be delayed by intervening at the stage of impaired glucose tolerance/impaired fasting glucose with lifestyle change and if type 2 diabetes is adequately managed from diagnosis diabetes complications can be avoided.

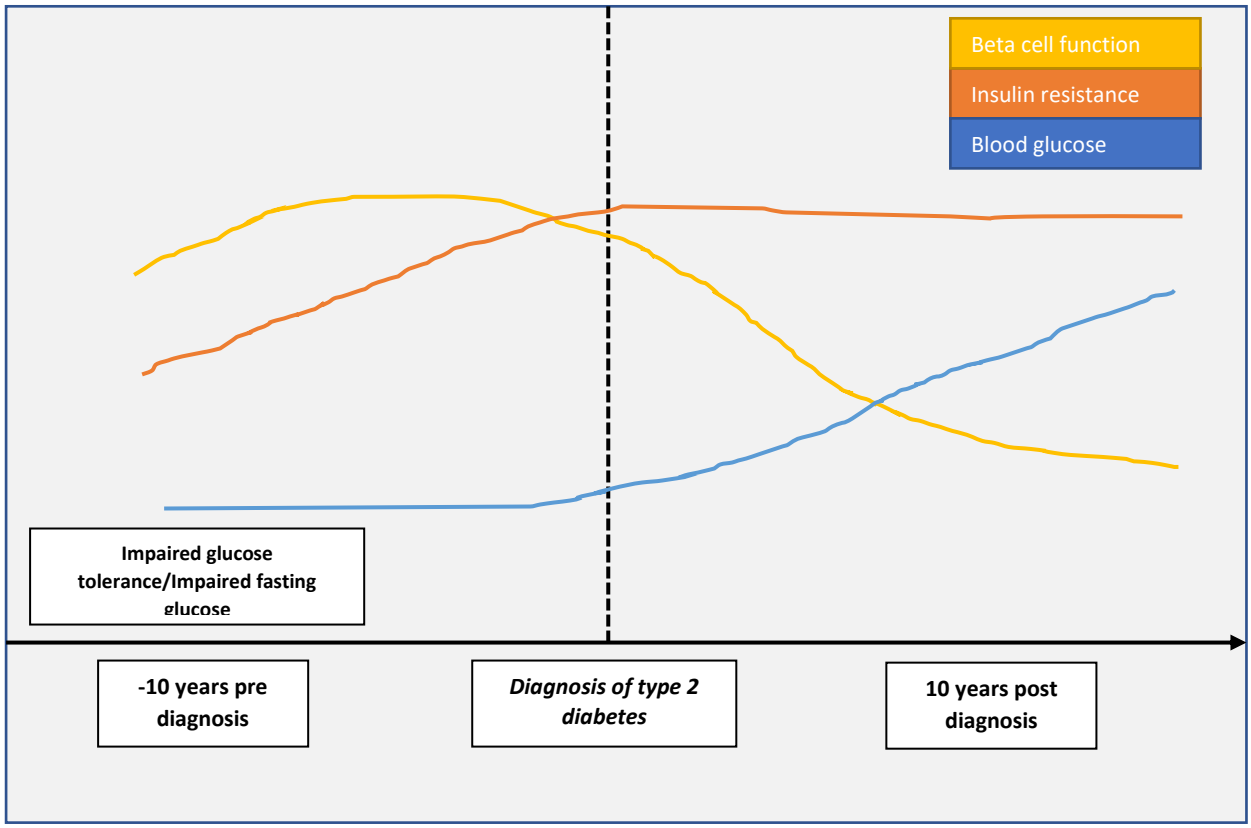

Figure 1.1- *The progression of type 2 diabetes*

Globally, it is estimated 510 million people may have type 2 diabetes by 2030 (Basu et al., 2019). The increasing prevalence of type 2 diabetes is accounted for by an ageing population and rising numbers of people who are overweight and obese (González,

Johansson, Wallander, & Rodríguez, 2009), and these are the main risk factors for type 2 diabetes. More than 80% of people with type 2 diabetes at diagnosis are overweight and this increases insulin resistance (Stringhini et al., 2012). Other risk factors for type 2 diabetes include modifiable risk factors such as sedentary lifestyle, smoking, previous impaired glucose tolerance or impaired fasting, elevated triglycerides, low levels of high-density lipoprotein cholesterol, hypertension, inflammation. Non-modifiable risk factors include sex, ethnicity, family history of type 2 diabetes, history of gestational diabetes, polycystic ovary syndrome (Chen, Magliano, & Zimmet, 2012). In Asia, although the rate of obesity is lower than in Europe, type 2 diabetes is developed in individuals with a lower body mass index (Yoon et al., 2006). This can be accounted for by a higher fat percentage at each body mass index category than Europeans causing more insulin resistance and hence the onset of type 2 diabetes (Deurenberg, Deurenberg-Yap, & Guricci, 2002).

1.2. Long term complications in type 2 diabetes

Type 2 diabetes is associated with both microvascular (damage to smaller blood vessels) and macrovascular (damage to larger blood vessels) complications, and these can impact quality of life, and risk of mortality (Deshpande, Harris-Hayes, & Schootman, 2008). High blood glucose levels and low-density cholesterol lead to chronic inflammation (atherosclerosis) which narrows arteries and decreases blood flow (Grundy, 1993; Yan, Ramasamy, Naka, & Schmidt, 2003) resulting in a heart attack or stroke (macrovascular complications) (Deshpande et al., 2008). The high concentration of blood glucose molecules can also damage smaller blood vessels, destroying blood vessel cells, decreasing blood flow resulting in tissue death (Loomans et al., 2004). Microvascular complications include retinopathy (damage to the retina of the eyes), neuropathy (damage to nerves), and nephropathy (deterioration of kidney function). Progression of diabetes complications can be delayed through appropriate type 2 diabetes treatment and achieving optimal glycaemic levels (Ohkubo et al., 1995).

1.3. Clinical targets for people with type 2 diabetes

The main targets set for people with type 2 diabetes are for blood pressure, cholesterol and glycaemia, achieving these targets reduces the risk of cardiovascular disease and diabetes complications (Gæde, Lund-Andersen, Parving, & Pedersen, 2008; Oellgaard et al., 2018). The target blood pressure is ≤135/85 mmHg and for cholesterol ≤4.9 mmol/l (Oellgaard et al., 2018).

HbA1c (glycated haemoglobin) is the standard measure of glycaemia (also referred to as glycaemic levels), representing glucose concentration in the blood over ~3 months (Little & Sacks, 2009). A series of trials have influenced HbA1c targets for type 2 diabetes over the years including the UK Prospective Diabetes Study (UKPDS(UKPDS, 1998b)) published in 1998; Diabetes Control and Complications Trial (DCCT(DCCT, 1993)); the Action in Diabetes and Vascular Disease Preterax and Diamicron MR Controlled Evaluation (ADVANCE(Patel & Group, 2007)) trial; and the Action to Control Cardiovascular Risk in Type 2 Diabetes (ACCORD(ACCORD, 2008)) trial. Study characteristics are summarised in table 1.1.

Table 1.1- *Summary of type 2 diabetes trials that influence HbA1c targets*

Trial	**Country**	**Study design**	**Outcomes**	**Sample size**
UKPDS	UK	10-year cohort	Incidence of microvascular and macrovascular complications	5102
ADVANCE	20 countries in Asia, Europe, North American, and Australia	Randomised controlled trial (intensive HbA1c target versus standard HbA1c target)	Incidence of microvascular and macrovascular complications	10,000
ACCORD	USA and Canada	Randomised controlled trial (intensive HbA1c target versus standard HbA1c target)	Rate of cardiovascular events	10, 251
DCCT	USA and Canada	Randomised controlled trial (intensive therapy [3+ daily injections] versus standard treatment [1 or 2 daily injections])	Incidence of microvascular disease	1441

The UKPDS (1998) demonstrated that a 1% reduction in HbA1c reduces the risk of microvascular disease by 25% (UKPDS, 1998b), this is similar to DCCT where 2% reduction in HbA1c led to 50% reduction in microvascular disease (DCCT, 1993). In addition, the UKPDS 1998 trial went on to find that tight HbA1c leads to a reduction in microvascular and macrovascular disease (Stratton et al., 2000). The ADVANCE trial expanded on UKPDS findings where intensive therapy (≤48 mmol/mol) had a 10% relative reduction in combined macrovascular and microvascular events compared with standard therapy. However, there was no difference between groups in rates of macrovascular events alone, and the combined result was accounted for by a significant reduction in nephropathy,

showing greater clinical benefits of intensive therapy for microvascular complications than macrovascular complications. The ADVANCE trial supports the glycaemic target of 48-53mmol/mol (Heller & Group, 2009). The ACCORD trial examined whether intensive therapy could also have benefits for macrovascular complications e.g. cardiovascular events. People with type 2 diabetes with increased cardiovascular risk were recruited and assigned to intensive therapy (HbA1c target <42 mmol/mol) or standard therapy (HbA1c target 53-63 mmol/mol). In the intensive therapy condition, cardiovascular deaths increased by 35% and all-cause mortality by 22% compared with standard therapy (ACCORD, 2008). Initially, it was thought severe hypoglycaemia and weight gain contributed to increased mortality but a post hoc analysis revealed this was not the case (ACCORD, 2016) and the most likely reason was persistently higher HbA1c levels (Riddle et al., 2010). It was concluded that for people with type 2 diabetes at high risk for cardiovascular events, optimal HbA1c targets should be 58mmol/mol and further reductions could put them at risk of mortality (ACCORD, 2017). A retrospective cohort study supported these findings in addition to finding a U-shaped association where low (43-49 mmol/mol) and high HbA1c (87-99 mmol/mol) were associated with all-cause mortality. The lowest risk of all-cause mortality was at around 58 mmol/mol (Currie et al., 2010).

The National Institute for Health and Care Excellence (NICE) guidelines recommend a HbA1c target of 48 mmol/mol managed with lifestyle and monotherapy (not associated with hypoglycaemia) (NICE, 2015). If someone with type 2 diabetes is treated with any drug associated with hypoglycaemia then their recommended HbA1c target is 53 mmol/mol. If HbA1c rises to 58 mmol/mol on any treatment, then treatment should be intensified. NICE guidelines also advise setting individualised targets based on 'personal preferences, comorbidities, risks from polypharmacy, and their ability to benefit from long-term interventions because of reduced life expectancy' (NICE, 2015). A consensus report of ADA and European Association for the Study of Diabetes (EASD) also promotes individualised treatment plans and glycaemic targets for type 2 diabetes called the 'goals of care' to prevent diabetes complications and maintain quality of life. The 'goals of care' are based on individual characteristics (lifestyle, comorbidities, age, HbA1c, weight, motivation, mental health), side effects of medications, the complexity of treatment, availability and cost of treatment, a treatment which will optimise adherence and persistence, shared-decision making plans and goals, and available ongoing support (Davies et al., 2018).

1.4. Treatment of type 2 diabetes

Type 2 diabetes is a cardiovascular disease and the aims of treatment are 3-fold to normalise: blood pressure, cholesterol, and glycaemia. Blood pressure can be lowered through physical activity, low salt diet, smoking cessation, reduction in alcohol, weight loss, and antihypertensive medication (Rayner, Allender, Scarborough, & Group, 2009). Cholesterol can be normalised through a high-fibre diet, diet low in saturated fats, increased physical activity, and cholesterol-lowering medication such as statins (Zipes, Libby, Bonow, Mann, & Tomaselli, 2018).

Type 2 diabetes treatment aims to reduce glycaemia and insulin resistance. Beta cell deterioration and increase in insulin resistance can be prevented with intensive weight-loss around diagnosis, though this is often not achieved (Dyson et al., 2011; Lean et al., 2018). The usual treatment pathway for people with type 2 diabetes is lifestyle modification (weight loss, reducing sedentary lifestyle), followed by oral antidiabetic medications (OADs). The most commonly prescribed OADs to reduce glycaemia are sulphonylureas (e.g. gliclazide) and most commonly used to reduce insulin resistance are biguanides (e.g. metformin) or Dipeptidyl peptidase-4 (DPP-4) inhibitors (e.g. sitagliptin).

Insulin injection therapy also reduces glycaemia. Insulin treatment is often required around 5-10 years from diagnosis (Khunti, Damci, et al., 2012; Turner, Cull, Frighi, Holman, & Group, 1999), when beta cell function has declined to 15 to 20% of normal function (Lebovitz, 1999). In the UK, NICE guidelines recommend insulin therapy as a second intensification of drug treatment, where someone with type 2 diabetes is on 2 OADs in addition to HbA1c being 58mmol/mol or above (NICE, 2015). An alternative recommended intensification at this point could also be 3 OADs or OADs in combination with injectable incretin mimetics (figure 1.2). Injectable incretin mimetics or glucagon-like peptide-1 receptor agonists (GLP-1 RAs) help decrease insulin resistance and work by increasing the hormone incretin which is involved in producing insulin and reduce glucose produced by the liver (Nielsen, 2005). Other worldwide guidelines also recommend insulin as the second intensification of drug treatment (ADA, 2016; Aschner, 2017; CDA, 2018; Garber et al., 2017; Mosenzon, Pollack, & Raz, 2016; NICE, 2015). American Diabetes Association (ADA) and Korean Diabetes Association (KDA) recommend insulin therapy combined with 1 OAD if HbA1c is 75mmol/mol or above (ADA, 2016; Lee et al., 2017). Canadian, International Diabetes Federation (IDF), and KDA guidelines recommend immediate use of insulin in people with metabolic decompensation or presence of hyperglycaemia with symptoms (Aschner, 2017; CDA, 2018; Lee et al., 2017).

Diabetes treatment can normalise glycaemia and limit hyperglycaemia and hypoglycaemia. Hyperglycaemia is defined as having a blood glucose of ≥11.1 mmol/L (WHO, 1999). Hypoglycaemia is defined as having a blood glucose reading of <3.5mmol/L, it can be caused by an excess of insulin, increased physical activity and lower carbohydrate intake. Warning symptoms that indicate hypoglycaemia can include but are not limited to: sweating, fatigue, dizziness, blurred vision, increased heart rate (Frier, 2009). There are several variables which can impact blood glucose, increase risk of hypoglycaemia or hyperglycaemia including diet (foods containing carbohydrate or protein); physical activity; dose, timing and frequency of diabetes treatment; side effects of medications; hormonal changes (stress, illness, menstrual cycle); and dehydration (Davies et al., 2018; Nathan et al., 2009), all of which need to be considered in the treatment of people with type 2 diabetes.

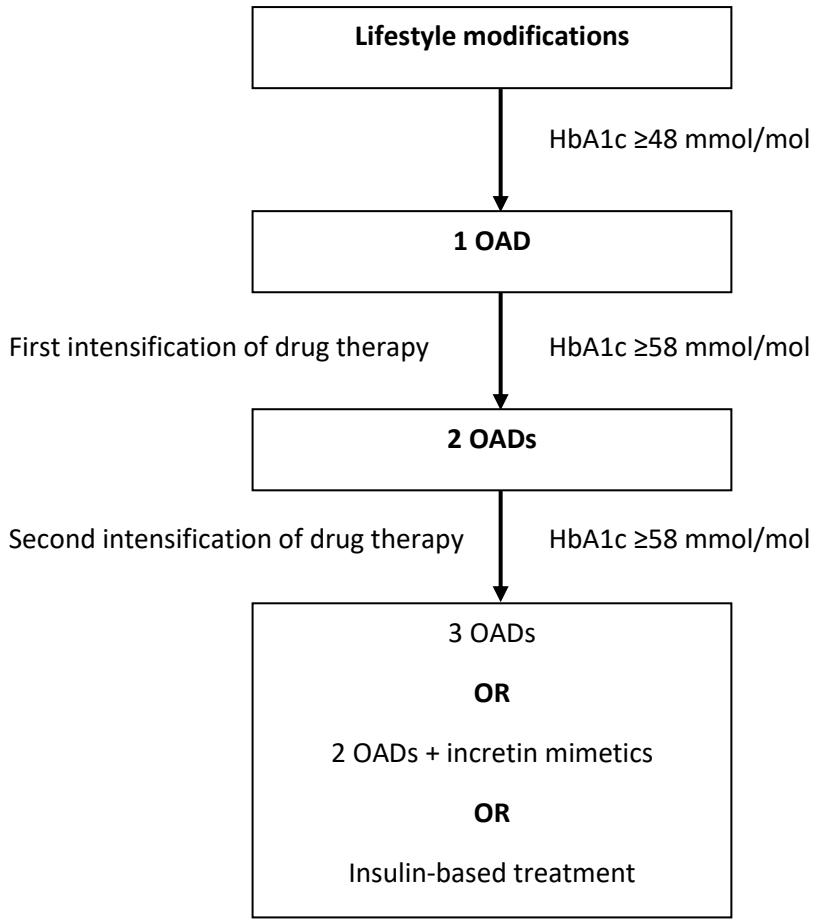

Figure 1.2- *NICE guidelines for treatment progression for people with type 2 diabetes*

1.5. Using insulin as a treatment for people with type 2 diabetes

Though insulin therapy makes hypoglycaemia more likely, it is the most intensive treatment for diabetes in terms of lowering blood glucose and therefore is most likely to achieve HbA1c targets, (Davies et al., 2018; Nathan et al., 2009). Insulin therapy is associated with improved HbA1c (Al Mansari et al., 2018; Asche, LaFleur, & Conner, 2011; Ayyagari et al., 2015; Caballero, 2009; Cramer & Pugh, 2005; Donnelly, Morris, Evans, & collaboration, 2007; Hajós et al., 2011; Mashitani et al., 2013; Rajagopalan, Joyce, Ollendorf, & Murray, 2003) and lower risk of diabetes complications (Caballero, 2009; Turner et al., 1999; UKPDS, 1998b). Qualitative research eliciting views of people with type 2 diabetes has identified positive benefits of insulin such as perceptions of relief after taking first insulin injection; more energy; and perceived risk reduction of long-term complications (Holmes-Truscott, Browne, & Speight, 2016; Holmes-Truscott, Skinner, Pouwer, & Speight, 2015).

1.5.1. Insulin regime for people with type 2 diabetes

Insulins are categorised into 3 different types depending on the duration of effect: long-acting; intermediate-acting; and short-acting. In type 2 diabetes, NICE guidelines recommend starting with Neutral Protamine Hagedorn (NPH; intermediate-acting) as basal insulin in combination with Metformin (unless intolerance) (NICE, 2015). NPH plus short-acting insulin is recommended separately or as a pre-mixed formula if HbA1c is ≥75mmol/mol. Alternatively, insulin detemir or insulin glargine (long-acting analogue insulin) should be prescribed if the person with type 2 diabetes needs help from someone else to inject insulin (as this reduces insulin injection frequency); or they are experiencing recurrent hypoglycaemia because these formulations have a flatter profile of action. Premixed insulin that includes short-acting insulin is recommended if there is a preference for injecting before a meal, hypoglycaemia is frequent, or blood glucose rises after the main meal. There should be a switch from NPH to insulin detemir or insulin glargine if target HbA1c cannot be reached and frequent hypoglycaemia is experienced. For people on basal insulin (NPH insulin, insulin detemir or insulin glargine), if HbA1c targets are not being met and there is a rise in post-prandial blood glucose then short-acting insulin before meals is recommended, a basal-bolus regime.

1.5.2. Cost-effectiveness of insulin treatment

In the UK, type 2 diabetes costs the national health service (NHS) around £8.8 billion per year (Hex, Bartlett, Wright, Taylor, & Varley, 2012), 80% is spent on treating diabetes

complications (e.g. cardiovascular, inpatient days, renal disease, neuropathy, stroke, foot ulcers and amputations etc) and the remainder on type 2 diabetes treatment (e.g. primary care services, prescriptions, influenza immunisation, medical exemption, smoking cessation programmes, diabetes education programmes, retinopathy screening, and blood glucose monitoring). Some evidence suggests insulin might not be cost-effective, accounted for by increased prescription costs (insulin and increased blood glucose monitoring equipment) and increased healthcare utilisation (Bexelius, Lundberg, Wang, Berg, & Hjelm, 2013; Brismar et al., 2013; Brixner et al., 2019). These studies were conducted in Sweden and the USA where the cost to the person with diabetes might be higher owing to healthcare insurance plans as compared with government-funded health service available in the UK. However, a UK-based study also found insulin is not cost-effective long-term (Valentine et al., 2015). The authors suggest the reason for this finding could be explained by data from trials over real-world practice. Studies often sampled people with type 2 diabetes and suboptimal HbA1c and insulin intensification was late in the progression of type 2 diabetes, resulting in modest improvements in glycaemia and reduced cost-effectiveness. On the other hand, there is evidence which indicates insulin therapy for people with type 2 diabetes is associated with reduced healthcare costs (Almbrand, Johannesson, Sjostrand, Malmberg, & Ryden, 2000; Aloumanis, Benroubi, Sourmeli, & Drossinos, 2013; Kleinman, Schaneman, & Lynch, 2008; Levin et al., 2011; Liebl, Khunti, Orozco-Beltran, & Yale, 2015; Rosenblum & Kane, 2003; Xie, Wei, Pan, & Baser, 2013). Lower healthcare costs with insulin therapy for type 2 diabetes is associated with early initiation (Liebl et al., 2015), low rates of and less severe hypoglycaemia (Bell et al., 2015; Heller, Frier, Herslov, Gundgaard, & Gough, 2016; Meneghini, Lee, Gupta, & Preblick, 2018; Parekh, Ashley, Chubb, Gillies, & Evans, 2015; Ridderstrale, Jensen, Gjesing, & Niskanen, 2013; Xie et al., 2013), and use of long-acting insulin such as insulin detemir (Borah et al., 2009; Ridderstrale et al., 2013) or insulin glargine (Dailey & Strange, 2008; Levin et al., 2011).

1.6. Problems associated with insulin treatment in type 2 diabetes

Potential problems with insulin treatment for people with type 2 diabetes include: delay in initiating insulin treatment, psychological aspects of insulin use, suboptimal HbA1c, adherence and persistence to insulin, and clinical inertia.

1.6.1. Delay in initiating insulin treatment

Even though insulin therapy is associated with improved diabetes outcomes and cost-effectiveness, as described in the previous sections, the delay in initiating insulin therapy in

the UK is significant (Khunti, Damci, et al., 2012; Rubino, McQuay, Gough, Kvasz, & Tennis, 2007). Studies report between 25-48% of people with type 2 diabetes refuse or are unwilling to initiate insulin therapy (Holmes-Truscott, Skinner, Pouwer, & Speight, 2016; Hosomura et al., 2017; Khan, Lasker, & Chowdhury, 2008; Larkin et al., 2007; Machinani, Bazargan-Hejazi, & Hsia, 2013; Polonsky, Fisher, Guzman, Villa-Caballero, & Edelman, 2005; UKPDS, 1998b). Insulin is likely to be started later than recommended by international guidelines (Costi, Dilla, Reviriego, Castell, & Goday, 2010), with some evidence suggesting insulin therapy in type 2 diabetes is only initiated when HbA1c is above 86 mmol/mol (10%) (Zografou, Strachan, & McKnight, 2014). Delay in initiating insulin therapy can be associated with the psychological aspects of insulin use (Hessler et al., 2018).

1.6.2. Psychological aspects of insulin use

There are many psychological aspects of insulin-taking for people with type 2 diabetes including needle phobia, hypoglycaemia, and psychological insulin resistance.

1.6.5.1. Needle phobia

In the general population, the prevalence of needle phobia has been reported at around 22% (Wright, Yelland, Heathcote, Ng, & Wright, 2009), which is higher in females and people of younger age (McLenon & Rogers, 2019; Wright et al., 2009). Needle phobia is associated with anxiety, sweating, and difficulties breathing (McLenon & Rogers, 2019; Wright et al., 2009). A review found the prevalence of needle phobia in people with diabetes ranges from 1.3-41.7%, however, this includes type 1 diabetes studies (McLenon & Rogers, 2019). Considering people with type 2 diabetes, needle phobia is often cited as a reason for preventing insulin initiation which has negative consequences on glycaemia (Fu, Wong, Chin, & Luk, 2015; Haque, Navsa, Emerson, Dennison, & Levitt, 2005; Karter et al., 2010; Polonsky & Jackson, 2004).

1.6.5.2. The psychological aspects of hypoglycaemia

Hypoglycaemic events are associated with a delay in initiating insulin treatment, higher HbA1c prior to therapy intensification, and lack of healthcare professional support (Hosomura et al., 2017; Mauricio et al., 2017). There are particular psychological consequences of hypoglycaemia such as anxiety (Polonsky, Fisher, Hessler, & Edelman, 2015; Snoek, Hajos, & Rondags, 2014), depressive symptoms (Barendse, Singh, Frier, & Speight, 2012), social isolation, embarrassment, stress (Snoek et al., 2014) and diabetes burnout (Polonsky, 1999). These are particularly relevant concerning insulin as this treatment has an increased risk of hypoglycaemic events compared with other type 2 diabetes treatments (UKPDS, 1998b).

1.6.5.3. Psychological insulin resistance

Psychological insulin resistance has been extensively researched and is defined as an opposition to initiating insulin treatment or ongoing therapy due to negative beliefs surrounding insulin (Petrak, Herpertz, Stridde, & Pfützner, 2013; Peyrot et al., 2005; Polonsky, Hajos, Dain, & Snoek, 2011). Psychological insulin resistance is detrimental to physical and mental health as it is associated with diabetes complications (Holmes-Truscott, Skinner, et al., 2016), depressive symptoms (Larkin et al., 2007; Makine et al., 2009; Woudenberg, Lucas, Latour, & Scholte op Reimer, 2012) and diabetes distress (Chen et al., 2011; Hermanns, Mahr, Kulzer, Skovlund, & Haak, 2010; Holmes-Truscott, Skinner, et al., 2016; Makine et al., 2009; Polonsky et al., 2011; Snoek, Skovlund, & Pouwer, 2007; Woudenberg et al., 2012). Psychological insulin resistance can be categorised into three categories: emotional; cognitive; and social (Gherman, Veresiu, et al., 2011), summarised in *figure 1.3*.

Emotional psychological insulin resistance includes anxiety towards treatment for example: ***fear of injections, or blood*** (Berard et al., 2018; Bogatean & Hâncu, 2004b; Ellis, Mulnier, & Forbes, 2018; Fu et al., 2015; Goderis et al., 2009; Haque, Emerson, Dennison, Navsa, & Levitt, 2005; Hassali et al., 2014; Hayes, Fitzgerald, & Jacober, 2008; Hussein et al., 2019; Jeavons, Hungin, & Cornford, 2006; Karter et al., 2010; Khan et al., 2008; Khunti, Davies, & Khunti, 2015; Lakkis, Maalouf, Mahmassani, & Hamadeh, 2013a; Lee, Lee, & Ng, 2012; Nadasen & Naidoo, 2012; Nakar, Yitzhaki, Rosenberg, & Vinker, 2007; Phillips, 2007; Polinski et al., 2013; Ratanawongsa et al., 2012; Ross, 2013; Tan, Tan, & Yeo, 2003; Taylor et al., 2017); **a *sense of personal failure towards diabetes self-management*** (Bogatean & Hâncu, 2004b; Brod, Alolga, & Meneghini, 2014; Brod, Kongsø, Lessard, & Christensen, 2009; Ellis et al., 2018; Jeavons et al., 2006; Karter et al., 2010; Khunti et al., 2015; Lee et al., 2012; Oliveria et al., 2007; Peyrot & Rubin, 2007; Peyrot et al., 2005; Polonsky & Jackson, 2004; Rebolledo & Arellano, 2016; Ross, 2013; Snoek et al., 2007; Tan et al., 2011; Tan et al., 2003; Taylor et al., 2017; Woudenberg et al., 2012); ***fear of side effects such as hypoglycaemia*** (Brod et al., 2009; DCCT, 1991; Ellis et al., 2018; Evans, Sharplin, et al., 2010; Hassali et al., 2014; Jeavons et al., 2006; Karter et al., 2010; Khan et al., 2008; Khunti et al., 2018; Lakkis et al., 2013a; Mauricio et al., 2017; Nakar et al., 2007; Petrak et al., 2013; Tan et al., 2011; Taylor et al., 2017) ***and weight gain*** (Berard et al., 2018; Brod et al., 2009; Brod, Pohlman, & Kongsø, 2014; Evans, Sharplin, et al., 2010; Haque, Emerson, et al., 2005; Khan et al., 2008; Khunti et al., 2015; Kostev, Dippel, & Rathmann, 2015; Lee et al.,

2012; Peyrot, Skovlund, & Landgraf, 2009; Polonsky et al., 2015; Ross, 2013; Taylor et al., 2017; Vallis, Jones, & Pouwer, 2014).

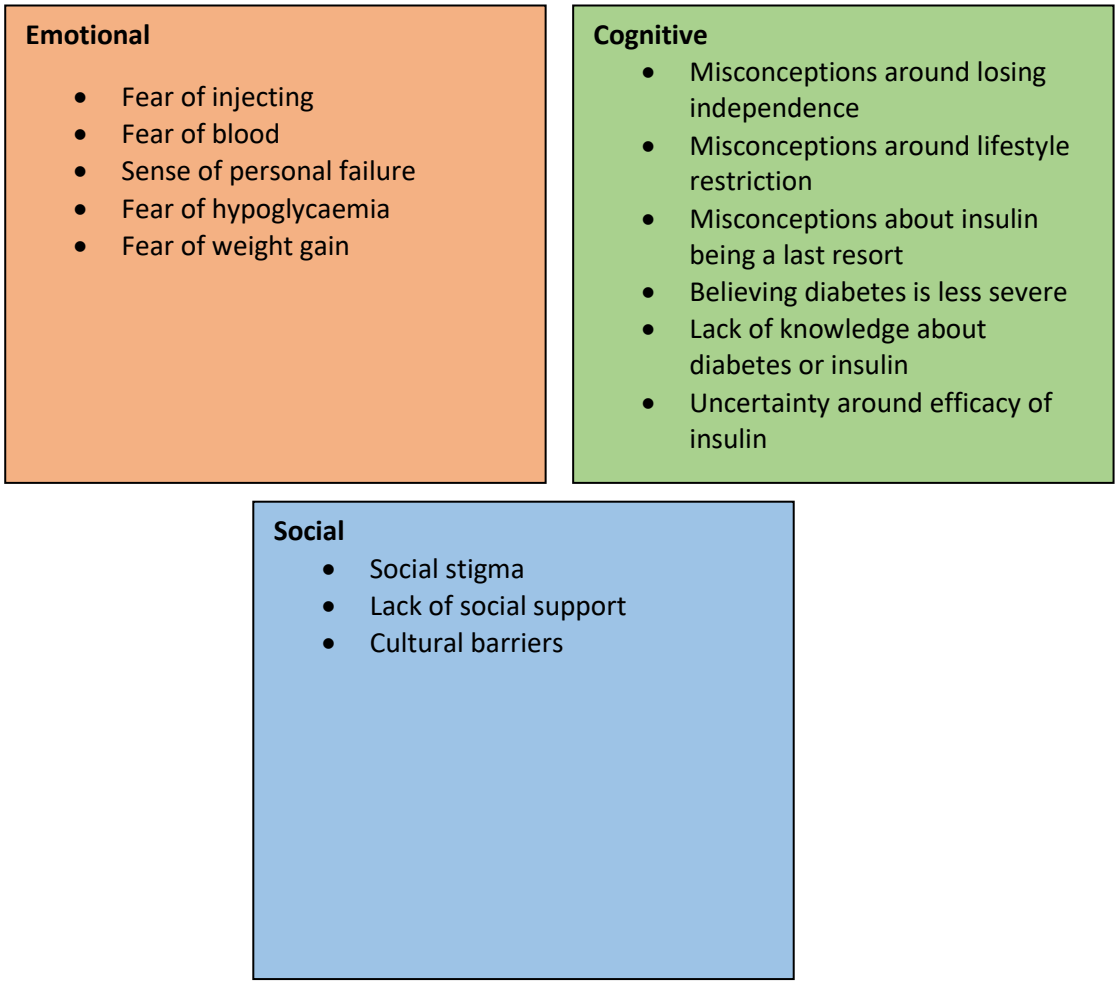

Figure 1.3- *Psychological insulin resistance categories*

A sense of personal failure stems from the idea the individual with type 2 diabetes believes it is their fault they have been unable to achieve optimal glycaemic levels target and therefore are to blame for requiring insulin therapy. Therefore, insulin is delayed as it is seen as a personal threat and confirmation of their 'failure' (Ng, Lai, Lee, Azmi, & Teo, 2015). There is mixed evidence regarding insulin therapy and weight gain (DCCT, 1988; Hermansen & Mortensen, 2007; Pontiroli, Miele, & Morabito, 2011). Insulin is associated with weight gain because insulin causes excess glucose entering cells to be stored as fat, in addition, insulin therapy allows blood glucose to enter cells instead of being lost through urine, therefore water retention prevents loss of energy through urine (Hermansen & Mortensen, 2007; Strachan & Frier, 2013). Also, hypoglycaemia requires glucose

consumption to stabilise blood glucose, this increases calorie intake, therefore if insulin therapy increases hypoglycaemic events then this could be a reason for gaining weight (Hermansen & Mortensen, 2007; Strachan & Frier, 2013). Long-acting insulins (Hartman, 2008; Holman et al., 2009; Khunti, Srinivasan, Shutler, & Davies, 2010; Nathan et al., 2009; Pontiroli et al., 2011; Yale et al., 2013), lower frequency of doses (Pontiroli et al., 2011), and insulin in combination with GLP-1 RAs prevent weight gain (Fuechtenbusch, Aberle, Heitmann, Nicolay, & Jung, 2019; Vanderheiden et al., 2016).

Cognitive psychological insulin resistance refers to misconceptions around insulin therapy for example: ***loss of independence, lifestyle restriction*** and/or ***concerns about independently administering insulin*** (Bogatean & Hâncu, 2004b; Brod et al., 2009; Escalada et al., 2016; Garnero et al., 2018; Hassali et al., 2014; Hayes et al., 2008; Hussein et al., 2019; Karter et al., 2010; Khan et al., 2008; Nadasen & Naidoo, 2012; Phillips, 2007; Tan et al., 2011); ***viewing insulin therapy as a last resort*** (Ellis et al., 2018; Haque, Emerson, et al., 2005; Hassali et al., 2014; Jeavons et al., 2006; Karter et al., 2010; Khan et al., 2008; Lakkis et al., 2013a; Mosnier-Pudar et al., 2009; Phillips, 2007; Ratanawongsa et al., 2012; Tan et al., 2011; Tan et al., 2003); ***uncertainty around efficacy of insulin*** (Hassali et al., 2014; Khan et al., 2008; Lakkis et al., 2013a; Lee et al., 2012; Peyrot et al., 2005); ***being asymptomatic or perceiving diabetes as less severe*** (Bogatean & Hâncu, 2004b; Garnero et al., 2018; Phillips, 2007); and ***lack of knowledge about diabetes or insulin*** (Goderis et al., 2009; Haque, Emerson, et al., 2005; Karter et al., 2010; Patel, Stone, Chauhan, Davies, & Khunti, 2012). Cognitive psychological insulin resistance can be linked to the necessity-concerns framework whereby an individual makes a treatment decision based on risk-analysis i.e. perceived risks versus benefits (Horne et al., 2013). Qualitative research finds that people with type 2 diabetes value the importance of addressing concerns around insulin therapy as well as learning about the necessity of insulin (Patel, Stone, McDonough, et al., 2015). However, this can be problematic in type 2 diabetes as people with suboptimal glycaemic levels can feel asymptomatic. If someone with type 2 diabetes does not experience hyperglycaemic symptoms then they could assume there are no problems, or that current treatment is adequate. Therefore, they may view that insulin treatment is not necessary especially if the risks of persistent high blood glucose levels are not communicated well.

Social psychological insulin resistance includes ***social stigma*** e.g. idea of injecting in public, and/or ***lack of social support*** (Bogatean & Hâncu, 2004b; Brod, Alolga, et al., 2014; Brod et al., 2009; Fisher et al., 2019; Hassan et al., 2013; Hussein et al., 2019; Janes, Titchener, Pere, Pere, & Senior, 2013; Khan et al., 2008; Lee et al., 2012; Mehmet, Hussey, & Ibrahim,

2015; Nadasen & Naidoo, 2012; Ong, Chua, & Ng, 2014; Patel et al., 2012; Phillips, 2007; Tan et al., 2011; Taylor et al., 2017). Social-psychological considerations are particularly relevant in insulin-taking behaviour as injectable therapies are perceived as more demanding than OADs and have a greater social impact (Peyrot, Harshaw, Shillington, Xu, & Rubin, 2012).

1.6.3. Sub-optimal HbA1c and insulin treatment

Even though research indicates, once insulin has been initiated, people are less negative towards insulin therapy (Cosson et al., 2019; Gherman & Alionescu, 2015; Hermanns et al., 2010; Holmes-Truscott, Furler, Blackberry, O'Neal, & Speight, 2017; Odawara, Ishii, Tajima, & Iwamoto, 2016; Perez-Nieves et al., 2016), have higher treatment satisfaction (Polonsky, Traylor, et al., 2014) and have improved quality of life (Hajós et al., 2011, 2012; Pouwer & Hermanns, 2009), many people with type 2 diabetes on insulin therapy have suboptimal glycaemic levels (Harris, Kapor, Lank, Willan, & Houston, 2010; Khunti et al., 2016; Tong, Vethakkan, & Ng, 2015). There could be several reasons which could account for this. Firstly, the progression and deterioration of beta cells, in general, make type 2 diabetes more difficult to manage, especially at the point where insulin therapy is required (UKPDS, 1998b). Secondly, in the UK, since the introduction of Quality and Outcomes Framework and the need for people with type 2 diabetes to meet HbA1c targets, it is now more common for practice nurses and general practitioners to treat people with type 2 diabetes on insulin in primary care rather than in secondary care by diabetes specialists (Burden & Burden, 2007; Chadder, 2013). In this case, the lack of specialist knowledge and familiarisation of insulin for people with type 2 diabetes on insulin could account for suboptimal HbA1c (Kunt & Snoek, 2009). On a patient-level, there are issues with adherence to insulin therapy (administering correct dose and frequency) and persistence (continuation of treatment) (Cramer et al., 2008; Garnero et al., 2018). Someone could be persistent i.e. continues with insulin over time, but nonadherent i.e. omits some doses. Or vice versa, a person could be adherent and take prescribed dose and frequency of insulin, but nonpersistent and discontinue insulin therapy. Both non-adherence and non-persistence negatively impacts glycaemic levels, increases the risk of mortality (Currie et al., 2012), and increases healthcare costs (Kennedy-Martin, Boye, & Peng, 2017).

1.6.4. Adherence to insulin treatment

The word ‘adherence’ is considered as stigmatising and has potentially detrimental effects on health outcomes when this type of language is used in clinical practice (NHSE, 2018). ‘Adherence’ is only used in this thesis owing to the term being a keyword/ Medical Subject

Headings (MeSh) term from previous research. In this context, adherence refers to optimal medication-taking behaviour, whereas non-adherence refers to suboptimal medication-taking behaviour.

There are varied reports of rates of adherence (30-85%) to insulin therapy in type 2 diabetes (Guerci, Chanan, Kaur, Jasso-Mosqueda, & Lew, 2019), these vary between studies based on the measure of adherence, type of insulin and population (Barag, 2011; Brod, Rana, & Barnett, 2012; Cooke, Lee, Tong, & Haines, 2010; Cramer et al., 2008; Davies et al., 2018; Donnelly et al., 2007; Farsaei, Radfar, Heydari, Abbasi, & Qorbani, 2014; Guerci et al., 2019; He, Chen, Wang, Wu, & Wu, 2017; Peyrot et al., 2017). Other variability can be accounted for there being no validated threshold for adherence to insulin therapy and the complexity of data collection which makes measuring adherence to insulin unreliable (Stolpe, Kroes, Webb, & Wisniewski, 2016).

Treatment demand and complexity of treatment including consideration of self-monitoring blood glucose, administering insulin, interaction with daily life and lifestyle such as diet (Davies et al., 2013), higher insulin dose and more frequent injections (Donnelly et al., 2007; Peyrot, Rubin, Kruger, & Travis, 2010) makes insulin adherence more difficult.

Around 20% people with type 2 diabetes report non-adherence via insulin omission e.g. skipping doses (Osborn & Gonzalez; Peyrot, Barnett, Meneghini, & Schumm-Draeger, 2012; Peyrot, Rubin, Kruger, et al., 2010; Rubin, Peyrot, Kruger, & Travis, 2009) or not injecting correct doses (Trief, Cibula, Rodriguez, Akel, & Weinstock, 2016). A self-report internet survey found people with type 2 diabetes are less adherent to insulin therapy than people with type 1 diabetes, perhaps due to people with type 2 diabetes having a 'residual insulin response' and therefore not having an immediate negative consequence of insulin omission that people with T1D experience (Peyrot, Rubin, Kruger, et al., 2010). Polonsky et al.'s evaluation of the literature proposes that the two key causes of treatment nonadherence in type 2 diabetes are: treatment burden (e.g. complexity of treatment, side effects, the cost to the patient) and beliefs around treatment (e.g. perceived efficacy, negative beliefs, healthcare professional relationship) (Polonsky & Henry, 2016).

Some reasons for insulin omission are proposed as unintentional, for example, forgetfulness due to distraction, busy schedules or memory deficits (Brod, Pfeiffer, & Harald Kongsø, 2014; Brod, Pohlman, et al., 2014; Ellis et al., 2018; Holmes-Truscott, Browne, et al., 2016). Forgetting could be explained by the complexity of some insulin regimes (Bermeo-Cabrera, Almeda-Valdes, Riofrios-Palacios, Aguilar-Salinas, & Mehta,

2018b; García-Pérez, Álvarez, Dilla, Gil-Guillén, & Orozco-Beltrán, 2013) . On the other hand, the complexity of insulin regime could account for nonadherence to insulin therapy such as difficulty self-titrating, which is not related to forgetting (Brod, Pohlman, et al., 2014; Brod et al., 2012; Cefalu et al., 2008; Ellis et al., 2018; Hortensius et al., 2012; Jenkins, Hallowell, Farmer, Holman, & Lawton, 2011; Leiter, Boras, & Woo, 2015; Ong et al., 2014; Vinter-Repalust, Petricek, & Katic, 2004).

Poor adherence is related to low socio-economic status (Bermeo-Cabrera, Almeda-Valdes, Riofrios-Palacios, Aguilar-Salinas, & Mehta, 2018a; Donnelly et al., 2007); lower-income (Peyrot, Rubin, Kruger, et al., 2010); higher education (Peyrot, Rubin, Kruger, et al., 2010); younger age (Donnelly et al., 2007; Fisher et al., 2019; Peyrot, Rubin, Kruger, et al., 2010), higher body mass index (Donnelly et al., 2007; Fisher et al., 2019); prior injectable use (Fisher et al., 2019); more than one event of severe hypoglycaemia (Fisher et al., 2019); negative perception of prior use of insulin of family/friends (Fisher et al., 2019); and ethnic minority (Cramer & Pugh, 2005). These factors should be taken into consideration when targeting people with type 2 diabetes to improve insulin adherence.

1.6.5. Persistence to insulin treatment

Non-persistence is also a problem in type 2 diabetes, after one year, 20-40% of people with type 2 diabetes discontinue insulin (Hadjiyianni et al., 2017; Miao, Wei, Lin, Xie, & Baser, 2014; Perez-Nieves et al., 2016; Roussel et al., 2016). Those who do not persist with insulin after 90 days of initiation are highly likely to restart it (Ascher-Svanum et al., 2014), owing to deteriorating blood glucose control. Other studies also find people with type 2 diabetes re-uptake insulin owing to suboptimal HbA1c, in addition, to supporting from healthcare professionals or friends/family (Idris et al., 2019). Persistence to insulin therapy is higher for long-acting insulin than intermediate-acting insulin which could be explained by reduced hypoglycaemia (Anderten, Dippel, & Kostev, 2015; Pscherer, Chou, Dippel, Rathmann, & Kostev, 2015), and lower insulin-injection frequency (Baser, Tangirala, Wei, & Xie, 2013; Donnelly et al., 2007; Guerci et al., 2019). For those who experience hypoglycaemia with insulin in the first 6 months, they are more likely to discontinue insulin within 12 months of initiation (Dalal, Kazemi, Ye, & Xie, 2017), though once the reason for hypoglycaemia has been resolved, re-uptake of insulin is more likely (Peyrot et al., 2017).

1.6.6. Clinical inertia

Healthcare professionals experience clinical inertia when a problem is recognised but they fail to act upon it (Phillips et al., 2001). A 2012 observational study of 10 countries (Canada, China, Germany, Israel, Italy, Poland, Portugal, Spain, Turkey, UK) revealed for all countries

(except Germany) most people with type 2 diabetes were on 2 OADs before initiating insulin (Khunti, Damci, et al., 2012). This could suggest insulin is being prescribed according to international guidelines as a second intensification of drug treatment. However, pre-insulin HbA1c was above target (>58 mmol/mol according to NICE guidelines) for all countries. Studies worldwide find insulin is prescribed when HbA1c is above target (Calvert, McManus, & Freemantle, 2007; Harris et al., 2010; Hosomura et al., 2017; Khunti, Damci, et al., 2012; Khunti et al., 2018; Khunti et al., 2016; Khunti, Wolden, Thorsted, Andersen, & Davies, 2014; Khunti et al., 2015; Lovshin & Zinman, 2013; Nichols, Koo, & Shah, 2007; Pantalone et al., 2019; Phillips et al., 2001). Even when HbA1c is above target, an audit in Canada found only 56% of healthcare professionals planned to intensify treatment, 5% planned to keep treatment the same, and the remaining healthcare professionals planned to communicate the importance of lifestyle modifications (Harris, Ekoe, Zdanowicz, & Webster-Bogaert, 2005). These studies provide evidence for a delay and clinical inertia towards initiating insulin therapy.

Phillips and colleagues suggested clinical inertia occurs for the following reasons: healthcare professionals overestimate their adherence to relevant guidelines; healthcare professionals believing their patient with type 2 diabetes is improving; and lack of healthcare professional training to achieve HbA1c targets (Phillips et al., 2001). Specialist knowledge could be a contributing factor with diabetes specialists being more likely to intensify treatment than non-specialists (Ellis et al., 2018; Peyrot et al., 2005; Reach, Le Pautremat, & Gupta, 2013; Shah, Hux, Laupacis, Zinman, & Van Walraven, 2005; Sterzi, Auziere, Jensen, & Lopes, 2017). In addition, clinical inertia can occur when healthcare professionals lack knowledge such as being unaware of HbA1c targets (Grant et al., 2007; Haque, Emerson, et al., 2005; Kunt & Snoek, 2009; Nakar et al., 2007; Zafar, Stone, Davies, & Khunti, 2015), therefore it is important for healthcare professionals to take accountability and obtain correct information regarding targets (Zafar et al., 2015). However, this could be difficult as there is mixed research evidence for the advantages of having tight blood glucose control in type 2 diabetes. For example, mixed results of clinical trials in improving complication status via intensive glycaemic targets such as ADVANCE (ADVANCE, 2008), ACCORD (ACCORD, 2008), and UKPDS (UKPDS, 1998a) trials. These mixed findings could lead to clinical inertia and delay of insulin treatment, as the clear benefits of intensive HbA1c via insulin therapy have not been clearly communicated (Bloomgarden, 2008; Khunti et al., 2016).

Clinical inertia is multifactorial and is associated with practical barriers such as time constraints (Grant et al., 2007; Kunt & Snoek, 2009; Tan et al., 2011), and perceived patient-barriers for example, fear of hypoglycaemia (Ellis et al., 2018; Grant et al., 2007; Haque, Emerson, et al., 2005; Sterzi et al., 2017), feelings of personal failure and potential impact on quality of life (Ellis et al., 2018; Lakkis et al., 2013a; Nakar et al., 2007; Ratanawongsa et al., 2012).

1.7. Strategies to overcome problems with insulin treatment

Researchers have made several suggestions around addressing problems associated with insulin use in type 2 diabetes. These are important on a patient and healthcare professional level when educating people with type 2 diabetes about the benefits of uptake and continued self-management of insulin treatment. Strategies are summarised in relation to avoiding clinical inertia, the importance of healthcare professional communication, and behavioural and psychological insulin interventions.

1.7.1. Strategies to avoid clinical inertia

Strategies have been proposed by (Shaefer, 2006), to avoid clinical inertia by healthcare professionals and include: establishing a set HbA1c goal (in accordance with relevant guidelines); defining a timeframe for this goal; and finally displaying the progress of the goal to oneself and people with type 2 diabetes (e.g. having results visible to both parties during follow-up). In support of these strategies, other research has found HbA1c can be improved by displaying progress and providing feedback on performance to health professionals (Parchman, Pugh, Romero, & Bowers, 2007) and people with type 2 diabetes (Ziemer et al., 2006). Insulin education for healthcare professionals should be created in multiple ways to increase insulin uptake for example, written, web-based, seminars or workshops (Peyrot, Rubin, & Khunti, 2010). However, clinical inertia is complex and addressing healthcare professional barriers in isolation may not resolve the problem, hence healthcare professional, patient, and system barriers should be considered all together to fully address the issue (Zafar et al., 2015).

1.7.2. Healthcare professional communication

Healthcare professional communication with people with type 2 diabetes is essential when addressing insulin treatment problems, and effective healthcare professional communication can positively influence insulin uptake, and insulin adherence and persistence (Ciechanowski, Katon, Russo, & Walker, 2001; Ellis et al., 2018; García-Pérez et al., 2013; Gherman, Schnur, et al., 2011; Tiv et al., 2012). On the contrary, poor healthcare professional communication regarding insulin can have a negative impact on people with

type 2 diabetes such as emotional response (fear and shock), lack of involvement in a decision regarding treatment, and gaps in knowledge regarding the importance and need for insulin (Given, McCay, Hill, O'Kane, & Coates, 2015).

Positive healthcare professional communication strategies in relation to insulin treatment include shared decision making (Peyrot, Barnett, et al., 2012; Polonsky & Henry, 2016) goal setting (Phillips, 2007), displaying adequate knowledge around insulin therapy (Bogatean & Hâncu, 2004a; Furler, Spitzer, Young, & Best, 2011; Goderis et al., 2009; Peyrot et al., 2005), using a blame-free approach (Garnero et al., 2018), and making time to answer questions and address concerns around insulin therapy (Stuckey et al., 2018; Tang et al., 2018). Good healthcare professional communication is related to lower diabetes distress and better diabetes self-care at any point of type 2 diabetes treatment intensification (Edelman et al., 2019).

The 'diabetes and emotional health guide for healthcare professionals' supporting adults with diabetes recommend steps for communicating with people with type 2 diabetes about psychological insulin resistance (Hendrieckx, Halliday, Beeney, & Speight, 2019). This guide uses a 7 A's mode: be **A**ware that people with type 2 diabetes experience psychological insulin resistance; **A**sk the person with type 2 diabetes about psychological insulin resistance e.g. "What are the benefits of insulin for you?"; **A**ssess psychological insulin resistance using a questionnaire (for example the Insulin Treatment Appraisal Scale; ITAS (Snoek et al., 2007)); **A**ssign to another healthcare professional e.g. diabetes specialist, mental health professional, or structured education group if needed; **A**dvise about psychological insulin resistance e.g. by normalising concerns, educate around diabetes progression and need for insulin; **A**ssist by creating an action plan; **A**rrange follow-up appointments to monitor progress. The 7 A's model is similar in approach to encouraging effective healthcare professional communication and are a guide for discussing insulin therapy with people with type 2 diabetes. However, this approach has not been empirically tested relating to addressing problems around insulin treatment.

1.7.3. Psychological and behavioural interventions

1.7.3.1. Psychological interventions which improve type 2 diabetes outcomes

Motivational interviewing is a common counselling technique which is non-judgemental and patient-centred aiming to resolve ambivalence (Rollnick & Miller, 1995). Ambivalence is highly relevant in the case of insulin therapy interventions as many uncertainties and concerns arise for people with type 2 diabetes (Ng et al., 2015). Motivational interviewing based interventions have been found to be effective in for people with type 2 diabetes in

improving blood glucose (A & Byron-Daniel, 2014; Chen, Creedy, Lin, & Wollin, 2012; Mulimba & Byron-Daniel, 2014; Song, Xu, & Sun, 2014; Winkley et al., 2019), and weight loss in type 2 diabetes (Ekong & Kavookjian, 2016; Mulimba & Byron-Daniel, 2014). People with type 2 diabetes are receptive to this therapy owing to feeling empowered; non-judgemental approach; being listened to; and preparing action plans and setting goals (Dellasega, Añel-Tiangco, & Gabbay, 2012). There is limited research around motivational interviewing and insulin use. Whilst motivational interviewing was encouraged in the 'Stepping Up' intervention (Furler et al., 2017), there was not an assessment of whether it was implemented. Therefore, there is a gap in research which examines whether motivational interviewing techniques are successful in improving problems associated with insulin use.

Cognitive behaviour therapy is another type of talking therapy which has been empirically tested in type 2 diabetes research. Cognitive behavioural therapy focuses on how cognitions (i.e. thoughts, attitudes or beliefs) affect behaviour and helps develop skills for dealing with problems. Cognitive behavioural therapy was initially developed to treat depression (Beck & Alford, 2009), because of how cognitions (thoughts, attitudes) can influence behaviour. Common unhelpful thinking styles (not limited to people with depression) include personalising (negatively attributing outcomes to oneself); catastrophising (thinking the 'worst-case scenario'); and all or nothing (holding high standards, might not engage in behaviour change unless success is certain). In systematic reviews of cognitive behavioural therapy or psychological interventions for people with type 2 diabetes, cognitive behavioural therapy is associated with improvements in depressive symptoms (Li et al., 2017; Uchendu & Blake, 2017; Wang, Tsai, Chou, & Chen, 2008), fasting glucose, quality of life, anxiety (Li et al., 2017), and HbA1c (Ismail, Winkley, & Rabe-Hesketh, 2004). Again, no individual studies specifically examine whether cognitive behavioural therapy is effective for resolving problems around insulin use.

1.7.3.2. Advantages of self-monitoring blood glucose in relation to insulin therapy

Psychological receptiveness to insulin therapy is associated to experiences of successful intensification of previous diabetes treatment in line with deteriorating blood glucose, in addition to accepting type 2 diabetes as a progressive condition (Jenkins, Hallowell, Farmer, Holman, & Lawton, 2010). Therefore, self-monitoring blood glucose is a behavioural technique recommended to emphasise type 2 diabetes progression and when intensification is required. However, there are potential barriers to self-monitoring blood glucose that need to be addressed including psychological issues (anxiety of testing and/or

result of the test, depression, self-esteem, self-efficacy, fear of needles, burden, avoidance) (Ciechanowski, Katon, & Russo, 2000; Egede & Osborn, 2010; Fisher, 2007; Hortensius et al., 2012; O'Neil et al., 2014; Ong et al., 2014; Polonsky, Fisher, Hessler, & Edelman, 2014; Schabert, Browne, Mosely, & Speight, 2013; Vincze, Barner, & Lopez, 2004; Weinger, Butler, Welch, & La Greca, 2005), inconvenience (Fisher, 2007; Kirk, Graves, Bell, Hildebrandt, & Narayan, 2007; Ong et al., 2014; Renard, 2005; Vincze et al., 2004), social stigma (Ong et al., 2014; Schabert et al., 2013; Tak-Ying Shiu, Kwan, & Wong, 2003), and not understanding the benefits (Polonsky, Fisher, et al., 2014). However, group type 2 diabetes education has been found to increase acceptance to self-monitoring blood glucose (Bruce, Davis, Cull, & Davis, 2003).

1.7.3.3. Current insulin education intervention research

A systematic review of factors affecting adherence to insulin therapy found diabetes education improves insulin adherence (Davies et al., 2013). In addition, higher treatment satisfaction for people with type 2 diabetes on insulin therapy was related to receiving diabetes education (Boels et al., 2017), however, for both these studies the type of diabetes education was not reported. Researchers have recommended psychological/behavioural educational strategies to overcome problems with insulin treatment including: demonstration of insulin injections with healthcare professional supervision (Allen, Zagarins, Feinberg, & Welch, 2017; Furler et al., 2011; Gherman, Schnur, et al., 2011; Jenkins et al., 2010; Phillips, 2007; Polonsky et al., 2019; Stuckey et al., 2018; Tan et al., 2011), insulin 'trial period', and (Gherman, Schnur, et al., 2011), and sharing of success stories of other people with type 2 diabetes on insulin (Allen et al., 2017). These strategies have not been empirically tested.

There is limited empirical evidence which specifically relates to interventions targeting the psychological aspects of insulin treatment. A DVD intervention for UK-based south Asian people with type 2 diabetes was designed to address misconceptions of insulin, which was then discussed with an healthcare professional (Patel, Stone, Hadjiconstantinou, et al., 2015). Misconceptions portrayed in the DVD included: severity of diabetes, fear of hypoglycaemia, sense of personal failure, link between insulin and complications, the pain of injections, administration difficulties, social stigma, source of insulin, and driving licence issues. Positive changes were seen in attitudes and insulin knowledge. The healthcare professionals delivering this intervention found the DVD time consuming, indicating this intervention not being feasible in real-world practice. A less time-intensive intervention could be printed materials such as an insulin tool called 'Questions about Starting Insulin:

Information on the Myths, Misconceptions and Clinical Realities about Insulin'. This again aimed to address concerns around insulin therapy as well as aid healthcare professional communication (Brod, Alolga, et al., 2014). Ten questions relating to insulin uptake barriers were generated from 13 focus groups of people with type 2 diabetes conducted across Germany, Sweden, The Netherlands, UK, and USA. Then, an interview with 4 clinical experts were responsible for producing answers to these questions. The questions related to barriers and misconceptions of insulin including difference between insulin and OADs, fear of side effects, link between insulin and complications, necessity, sense of personal failure, insulin dependence, insulin titration, lifestyle restrictions, and pain of injections. The limitation of this intervention, like Patel et al, is it only considered barriers to insulin initiation and not adherence or persistence issues, however some of the pre-initiation concerns might translate to self-management concerns e.g. concerns about weight gain (Holmes-Truscott et al., 2015). The advantage of this resource is it can be used to support different modes of type 2 diabetes education e.g. one-to-one, and group. A full evaluation of these two interventions is yet to be tested in a randomised controlled trial. Mathers et al did test their intervention in a randomised controlled trial (Mathers et al., 2012). This intervention involved healthcare professionals using a decision aid tool in a single consultation with insulin naïve people with type 2 diabetes to support shared decision-making around diabetes treatment choice. Though not limited to insulin therapy only, the intervention did result in improved knowledge, perception of consequences (for example, hypoglycaemia, weight gain and complications), and independent decision-making. Though this intervention does find advantages around shared decision making in type 2 diabetes education, the intervention did not improve HbA1c over the control group, nor measure psychological aspects of insulin use (e.g. psychological insulin resistance) as an outcome. A Romanian randomised controlled trial found individual sessions of structured education to initiate insulin in type 2 diabetes were effective in improving HbA1c 6 months later compared with less intensive education, however, there were no differences between groups in improving body weight or the number of hypoglycaemic episodes (Bala, Rusu, Moise, & Roman, 2019). Again, this study did not consider the psychological aspects of insulin use. None of these studies (Bala et al., 2019; Brod, Alolga, et al., 2014; Mathers et al., 2012; Patel, Stone, Hadjiconstantinou, et al., 2015) examine group insulin education.

1.7.4. Group diabetes education

The core rationale for group-based insulin education is social support from others in the same situation. Social support for people with type 2 diabetes is associated with reduced

HbA1c (Stopford, Winkley, & Ismail, 2013; Strom & Egede, 2012). Social factors also have an important role in insulin initiation, for example, family or peer support (Bogatean & Hâncu, 2004a; Burden & Burden, 2007; Farsaei et al., 2014; Nadasen & Naidoo, 2012; Patel et al., 2012; Phillips, 2007) and knowing others who take insulin (Bogatean & Hâncu, 2004a; Tan et al., 2011).

There is evidence of the efficacy of a group-based diabetes education programme people with type 2 diabetes called **D**iabetes **E**ducation and **S**elf-**M**anagement for **O**ngoing and **N**ewly **D**iagnosed (DESMOND) in weight loss, and positive illness beliefs (Davies et al., 2008; Khunti, Gray, et al., 2012a). No significant differences were found in HbA1c 12 months later between intervention and control however this could be accounted for by intervention baseline HbA1c values being higher. A real-world evaluation of DESMOND found a significant reduction in HbA1c (Chatterjee, Davies, Stribling, Farooqi, & Khunti, 2018). Systematic reviews and meta-analysis of studies worldwide find group-based type 2 diabetes education shows benefits in HbA1c, diabetes knowledge self-management skills, self-efficacy, weight, and treatment satisfaction compared with control conditions (Norris, Lau, Smith, Schmid, & Engelgau, 2002; Odgers-Jewell et al., 2017; Steinsbekk, Rygg, Lisulo, Rise, & Fretheim, 2012). Some of the studies criteria included people with type 2 diabetes on insulin therapy, though no studies related specifically to group-based insulin education.

There are existing group education programmes such as X-PERT Insulin (X-PERT Health) and the Injectable Therapies Toolkit (The DESMOND Collaborative), however, they do not specifically address psychological aspects of insulin use. A review of type 2 diabetes models of injectable therapy initiation found successful models included nurse-led group sessions (Appannah, Rice, & Ogrin, 2017).

1.8. Chapter summary

Insulin injection therapy is an inevitable treatment for many people with type 2 diabetes when beta cells have deteriorated to a point where other therapies cannot help them achieve optimal glycaemic levels. Insulin has been found to be effective in normalising blood glucose levels and this significantly reduces the risk of long-term complications. There is however a significant delay in initiating insulin therapy, accounted for largely by clinical inertia and psychological aspects of insulin use for people with type 2 diabetes. There are also problems with insulin use such as suboptimal HbA1c, adherence, and persistence to insulin treatment. Healthcare professional communication with people with type 2 diabetes and the delivery of insulin specific education is essential in resolving these

problems. Existing group insulin education needs to incorporate psychological aspects of insulin use before initiating insulin treatment with the aim of providing a strong foundation for supporting future adherence and persistence to insulin to improve type 2 diabetes outcomes. The overall aim of this thesis was to develop a group psychological intervention to optimise insulin initiation for people with type 2 diabetes. This was addressed through 4 studies whose aims, and objectives are outlined below.

1.10. Aims and objectives of the thesis

Study 1:

Aim: To examine the relationship between behaviour change technique categories and HbA1c in type 2 diabetes.

Objective 1: To extract which behaviour changes techniques underpin psychological interventions from a meta-analysis of 67 randomised controlled trials comparing psychological interventions to control to improve HbA1c in type 2 diabetes.

Objective 2: To conduct a meta-regression to determine the relationship between HbA1c and behaviour change technique category.

Objective 3: To conduct a meta-regression to determine the relationship between HbA1c and frequency of behaviour change techniques.

Study 2:

Aim: To examine the experiences of attending nurse-led group-based insulin start group education for people with type 2 diabetes.

Objective: To conduct a qualitative evaluation via one-to-one semi-structured interviews of the experiences of people with type 2 diabetes who have attended an insulin start group in south London.

Study 3

Aim: To examine the association between i) depressive symptoms, ii) diabetes distress iii) negative insulin beliefs on a) time to insulin-requiring status and b) time to insulin initiation.

Objective 1: To extract date of insulin-requiring status and insulin initiation from primary care medical records of the **SOU**th **L**ondon **D**iabetes (SOUL-D) cohort.

Objective 2: To conduct a survival analysis to determine time to insulin-requiring status from type 2 diabetes diagnosis of the SOUL-D cohort.

Objective 3: To conduct a survival analysis to determine time to insulin initiation from type 2 diabetes diagnosis of the SOUL-D cohort.

Objective 4: To conduct a survival analysis to determine time to insulin initiation from insulin-requiring status of the SOUL-D cohort.

Objective 5: To compare survival distributions between baseline psychological variable categorical groups (depressive symptoms, diabetes distress and negative insulin beliefs).

Objective 6: To conduct Cox regression analysis to determine the association between baseline psychological variable categorical groups (depressive symptoms, diabetes distress and negative insulin beliefs) and time to insulin-requiring status controlling for confounding variables.

Objective 7: To conduct Cox regression analysis to determine the association between baseline psychological variable categorical groups (depressive symptoms, diabetes distress and negative insulin beliefs) and time to insulin initiation controlling for confounding variables.

Study 4

Aim: To develop a nurse-led group psychological intervention to optimise insulin initiation for people with type 2 diabetes. The intervention is called **D**iabetes **I**nsulin **M**anagement **E**ducation (DIME).

Objective 1: To use effective behaviour change techniques from study 1 to underpin the DIME intervention.

Objective 2: To integrate views and suggestions from study 2 into DIME development.

Objective 3: To consider which psychological variables in study 3 impact insulin initiation in the development of DIME.

Objective 4: To use findings from studies 1-3 to inform the behaviour change wheel to identify relevant behaviour change techniques to underpin the DIME intervention.

Objective 5: To integrate psychological techniques used in previous diabetes education manuals to develop the DIME intervention.

Objective 6: To pilot test the DIME intervention on two groups of people with type 2 diabetes initiating insulin.

Study 5

Aim: To determine the acceptability of the pilot DIME intervention.

Objective 1: To qualitatively evaluate the experiences of people who attended the DIME pilot sessions.

Objective 2: To extract clinical data of the DIME exit interviewees to form case studies pre and post DIME attendance.

Chapter 2 : *A meta-analysis to determine the effectiveness of behaviour change techniques in psychological interventions to improve HbA1c for people with Type 2 diabetes mellitus.*

2.1. Chapter scope

This chapter describes study 1 of this thesis. This study extracts behaviour change techniques from the psychological intervention descriptions of trials from an existing systematic review and meta-analysis of psychological interventions to improve HbA1c in type 2 diabetes (Winkley et al., 2019), appendix 2.1. Study 1 of this thesis repeats a meta-analysis of HbA1c outcomes from the studies included in the existing review but with English language studies only (67 out of 70 studies). In addition, study 1 of this thesis conducts an additional analysis of the existing review to determine whether there is an association between behaviour change techniques and improvement in HbA1c.

2.2. Introduction

The behaviour change wheel is a model to explain behaviour that was created for the purpose of designing and evaluating behaviour change interventions (Michie, Atkins, & West, 2014). At the core of the behaviour change wheel is the COM-B behavioural model, COM-B refers to how **c**apability, **o**pportunity, and **m**otivation interact to influence **b**ehaviour. The capability component includes the physical (e.g. skill) and psychological (e.g. knowledge) ability to carry out a behaviour. The motivation component refers to the cognitive processes which allow someone to perform the behaviour, including automatic (e.g. emotional) and reflective (e.g. making plans) processes. The opportunity component is concerned with the social (e.g. norms) and physical (e.g. location) factors that make the behaviour possible to achieve (Michie, van Stralen, & West, 2011), figure 2.1.

The use of the behaviour change wheel has revolutionised the way science standardises, develops, evaluates, and reports complex behavioural interventions. A program of research that has stemmed from the behaviour change wheel is a standardised taxonomy that aims to describe specific active ingredients within interventions. This has been termed the Behaviour Change Technique Taxonomy version 1 (BCTTv1) (Michie et al., 2015). Behaviour change techniques can be defined as small, observable and replicable components of an intervention which can lead to a change in behaviour in an individual or group of people. The BCTTv1 comprises of 93 behaviour change techniques which are classified into 16 categories of change (figure 2.2).

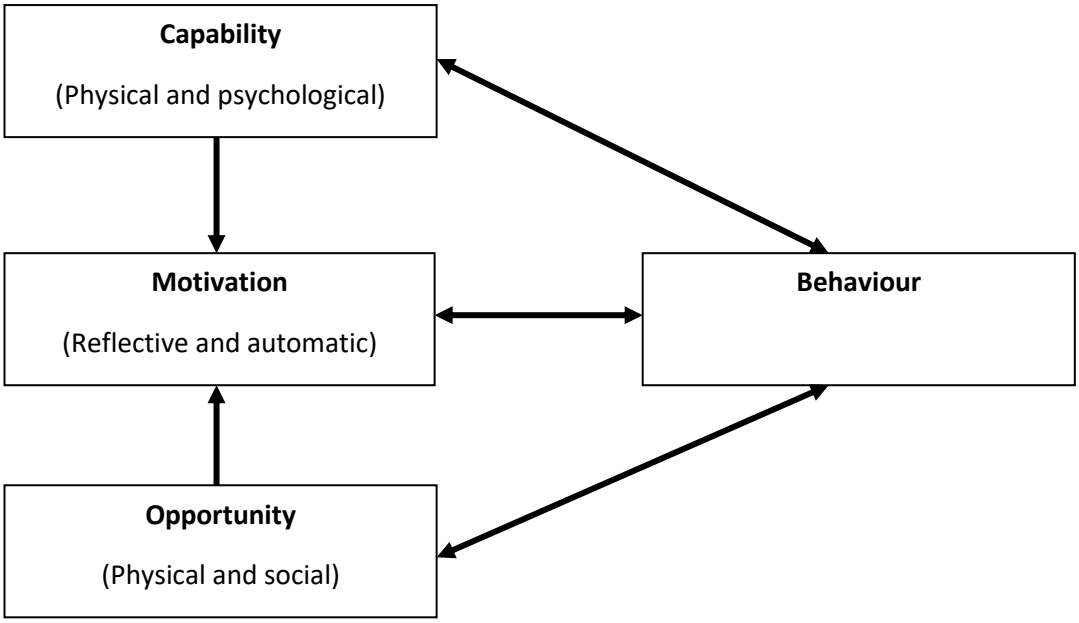

Figure 2.1-*The COM-B model*

1. Goals and planning	9. Comparison of outcomes
2. Feedback and monitoring	10. Reward and threat
3. Social support	11. Regulation
4. Shaping knowledge	12. Antecedents
5. Natural consequences	13. Identity
6. Comparison of behaviour	14. Scheduled consequences
7. Associations	15. Self-belief
8. Repetition and substitution	16. Covert learning

Figure 2.2- *Behaviour change techniques categories*

The use of these behaviour change techniques allows for a standardised language amongst health researchers and healthcare professionals when designing interventions and reporting findings. This ensures that the interventions can be replicated, therefore improving the fidelity of delivery and facilitating replicability, and evaluation (Dugdale et al., 2016).

There is some literature on behaviour change techniques and interventions to improve outcomes in type 2 diabetes. Studies found a higher frequency of behaviour change techniques used in behavioural interventions targeting physical activity and weight loss in type 2 diabetes was associated with better improvement in glycaemic levels (Avery, Flynn,

Van Wersch, Sniehotta, & Trenell, 2012) and weight loss (Hankonen et al., 2014). Behaviour change techniques in dietary focused interventions that are associated with improved glycaemic levels include: 'instruction on how to perform a behaviour' (shaping knowledge), 'behavioural practice/rehearsal' (repetition and substitution), 'demonstration of the behaviour' (comparison of behaviour), and 'action planning' (goals and planning) (Cradock et al., 2017). Behaviour change techniques associated with reduced fat intake in type 2 diabetes were associated with 'goals and planning', including 'goal setting' and 'review of behaviour/outcome goals' (Hankonen et al., 2014). A web-based intervention for people with type 2 diabetes which used the following behaviour change techniques were associated with improvements in behaviour change, well-being or clinical parameters: 'feedback on behaviour'(feedback and monitoring), 'information about health consequences'(natural consequences), 'problem-solving'(goals and planning), and 'self-monitoring of behaviour'(feedback and monitoring) (van Vugt, de Wit, Cleijne, & Snoek, 2013). A qualitative analysis extracting behaviour change techniques from implementation interventions (Presseau et al., 2015) based on studies identified in a systematic review (Tricco et al., 2012) found the most frequent behaviour change technique categories included: associations, natural consequences, shaping knowledge, antecedents, social support and goals and planning.

Psychological interventions such as cognitive behavioural therapy and counselling (e.g. motivational interviewing) are associated with an improvement in glycaemic levels for people with type 2 diabetes (Alam, Sturt, Lall, & Winkley, 2009; Ismail et al., 2004; Schmidt, van Loon, Vergouwen, Snoek, & Honig, 2018; Winkley et al., 2019). However, there is limited understanding of which behaviour change techniques underpin these psychological interventions aiming to improve glycaemic levels for people with type 2 diabetes. Coding interventions using specific behaviour change techniques ensures that future intervention design can develop more effective interventions owing to certainty around which techniques are the active ingredients of the intervention. This is opposed to counselling or cognitive behavioural therapy which are potentially broad in definition.

Study 1 of this thesis coded behaviour change techniques from psychological interventions descriptions from a recent existing systematic review of psychological interventions to improve HbA1c in type 2 diabetes (Winkley et al., 2019). The aim of this study was to examine the relationship between behaviour change technique categories and HbA1c in type 2 diabetes.

2.3. Methods

Winkley et al, 2019 reports a systematic review, aggregate meta-analysis, and network meta-analysis of psychological interventions to improve HbA1c in type 2 diabetes (Winkley et al., 2019). Study 1 of this thesis performs an aggregate meta-analysis of the English-language studies included in Winkley et al (Winkley et al., 2019). Here, the main methods of the Winkley et al are reported according to Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) checklist, appendix 2.2. This section also reports which studies and data were analysed for additional analysis in this thesis chapter (i.e. not included in Winkley et al, 2019).

2.3.1. Protocol and registration

A study protocol was registered with Prospective Register of Systematic Reviews (PROSPERO; CRD42016033619) detailing methods and analysis plan for the Winkley et al, systematic review and meta-analysis (Winkley et al., 2019). Additional analyses reported in this chapter were not detailed in the protocol.

2.3.2. Eligibility criteria

2.3.2.1. Types of studies

Randomised controlled trials of psychological interventions for people with type 2 diabetes were included (published and unpublished). Study designs which included no control group were excluded (e.g. pre-post observational and N-of-1 studies). Information could be extracted from multiple publications where relevant i.e. long-term follow-ups or protocols. English-language studies only were included in this thesis chapter (study 1). Three non-English language studies from the existing review (Winkley et al., 2019) were not included owing to difficulties finding BCTTv1 trained native translators.

2.3.2.2. Participants

Adults (≥18 years) diagnosed with type 2 diabetes were included. People with type 1 diabetes, pre-diabetes, impaired glucose tolerance, gestational diabetes, or other medical conditions were excluded. If studies included multiple conditions including type 2 diabetes, the study was included if separate analysis for people with type 2 diabetes was provided by trial authors.

2.3.2.3. Interventions

Inclusion of intervention was based on all the following criteria for a psychological intervention:

1) relied on a therapeutic reliance (based on communication between person[s] with type 2 diabetes and psychological intervention facilitator);

2) facilitated by psychology professionals (e.g. psychologist, therapist accredited or in training); or facilitators were trained in a psychological intervention by a psychology professional; or facilitators were supervised by a psychology professional;
3) underpinned by a psychological model;
4) aimed to improve emotional, cognitive or behavioural functioning.

Where a decision on inclusion could not be made based on reported intervention description, trial authors were contacted for more detail. Self-help interventions were excluded unless guided by a facilitator.

Control groups included: usual care (including enhanced usual care), waiting list control, and attention control (matching frequency and duration of sessions as psychological intervention) and diabetes education.

2.3.2.4. Outcomes

The primary outcome was change in glycaemic levels, HbA1c measured in % or mmol/mol.

2.3.3. Information sources

Studies were identified through electronic database searching, reviewing reference lists of included studies, and searching conference abstracts. The search was applied from January 2003 to July 2018 for MEDLINE (Ovid) Cumulative Index to Nursing and Allied Health Literature (CINAHL), The Cochrane Library, PsycINFO, EMBASE (Ovid), Cochrane Controlled Trials Register and Web of Science. The following conference abstracts were screened from 2012 to July 2018 to determine any unpublished work: Diabetes UK, the ADA, EASD, and the IDF. If work was unpublished, authors were contacted for full-text papers.

2.3.4. Search

The following key search terms were adapted for each database: ‘psychological therapies’, ‘mood disorders’, ‘diabetes mellitus’ and ‘clinical trials’. A full search strategy for MEDLINE is provided in appendix 2.3.

2.3.5. Study selection

Two researchers (RU and KW) independently searched the electronic databases and screened abstracts followed by full-text papers. A third researcher (KI) resolved any discrepancies over the decision of full-text article inclusion. Any ambiguity at abstract screening meant papers were included for full-text screening. There was high inter-reliability between researchers at full-text inclusion stage (Cohen’s kappa=0·95).

2.3.6. Data collection process

A data extraction form was developed in Microsoft Excel (based on a Centre for Reviews and Dissemination template) and was pilot tested on 10 randomly selected included studies, and refined. One researcher (RU) extracted data from all studies which was checked by a second researcher (KW), any disagreements were resolved by a statistician (DS) or psychiatrist (KI). If there were 3 or more study arms, the least and most intensive (according to frequency, duration and/or mode of interventions) were included for meta-analysis.

2.3.6.1. The additional data collection process

Two researchers (RU & DO) performed additional data collection to extract behaviour change techniques from psychological intervention descriptions of English-language studies included in the aggregate meta-analysis of the Winkley et al paper (Winkley et al., 2019). A second data extraction table was prepared in Microsoft Excel. These two researchers (RU & DO) were post-graduate health psychology researchers and were trained via online BCTTv1 training (BCTTv1, 2019). Behaviour change technique extraction was pilot tested on 10 studies independently and initial ratings were compared amongst researchers (RU & DO) to agree on interpretations and prevent future discrepancies. These studies were re-rated, and the remaining studies were independently coded before overall ratings were compared. A third researcher (KW) resolved any disagreements regarding behaviour change technique coding. Inter-rater reliability between the two researchers' coders was calculated to determine agreeability and was high (Cohen's kappa=0.96).

The psychological intervention description was examined in detail from sources available: published papers, supplementary materials, or study protocols. From intervention descriptions, relevant behaviour change technique descriptions were copied into the data extraction table. The BCTTv1 was reviewed several times to identify correct behaviour change techniques to match the language used in the intervention description. In some cases, it was relevant to code more than one behaviour change technique to an intervention excerpt. Also, multiple examples from an intervention excerpt could be applied to one behaviour change technique. The behaviour change technique must have been related to the intervention target behaviour or outcome hence behaviour change techniques were not coded with reference to research activity e.g. material reward for taking part in research (as opposed to material reward for engaging in the specific target behaviour such as physical activity). Behaviour change techniques could be extracted from tables outlining interventions, in these cases full phrases or sentences were not extracted

e.g. ‘action-planning’ but table text was required to match behaviour change technique taxonomy codes to be included (no inferences were made).

2.3.7. Data items

Information was extracted from each randomised controlled trial on:

1) Participants characteristics: mean age (years), type 2 diabetes duration (years), inclusion/exclusion criteria.
2) Psychological intervention and control group (as applicable) characteristics: name of intervention, frequency of sessions, duration of intervention, duration of each session, interventionist, mode of delivery (face-to-face; telephone), the format of delivery (one-to-one; group), fidelity assessment.
3) Outcomes characteristics: mean baseline and follow-up HbA1c (% or mmol/mol), the standard deviation of baseline HbA1c, timepoint of follow-up.
4) Publication characteristics: year of publication, country of data collection.

Information was extracted from descriptions of psychological interventions for the additional analysis of this thesis chapter which included: behaviour change techniques (multiple rows per study if multiple behaviour change techniques were coded), an example of the behaviour change technique from study transcript, and location of the behaviour change technique in the transcript.

2.3.8. Risk of bias in individual studies

Risk of bias was assessed using the Cochrane Handbook Tool for Risk of Bias (Higgins et al., 2011). The risk of bias assessment was determined independently by two researchers (RU & KW) and any discrepancies resolved by a third researcher (KI).

2.3.9. Summary measure and synthesis of results

Statistical analysis was conducted in STATA 15 (StataCorp, College Station, TX, USA). Effect sizes (Cohen’s d) were pooled in a random-effects meta-analysis of the standardised mean difference in HbA1c between baseline and follow-up (12 months or closest) between psychological intervention and control group for each trial (and overall effect size for all trials).

2.3.10. Risk of bias across studies

Publication bias was used to assess the risk of bias across studies. This was assessed using Egger’s publication bias (Egger, Smith, Schneider, & Minder, 1997), and the trim and fill method (Duval & Tweedie, 2000) to determine missing studies.

2.3.11. Additional analyses

Meta-regressions were performed to determine the association between study characteristics (psychological intervention category, behaviour change technique category, frequency of behaviour change technique per study, year of publication, and treatment fidelity) and treatment effect (HbA1c) (Sutton & Higgins, 2008). Five or more studies were necessary to conduct meta-regression (Borenstein, Hedges, Higgins, & Rothstein, 2011), therefore behaviour change techniques were categorised into 16 groups domains based on their mode of action to ensure enough studies per group to perform this analysis (Michie et al., 2014) (figure 2.2).

2.4. Results

2.4.1. Study selection

Thirty-one thousand and sixty-nine records were identified through electronic database searching (figure 2.3). After duplicates were removed 23080 records were screened and 67 English-language full-text papers were eligible for inclusion where HbA1c data was available for meta-analysis. Reasons for exclusion are reported in figure 2.3.

2.4.2. Study characteristics

Study characteristics are summarised in table 2.1. In this thesis chapter 67 out of the 70 previously reported studies were synthesised (Winkley et al., 2019). Three excluded studies were excluded as they were non-English language, these studies were in Spanish (n=1) (Muñoz-Flórez & Cortés, 2017) and Iranian (Farsi; n=2) (Davazdah Emamy, Roshan, Mehrabi, & Attari, 2009; Hamid, 2011).

2.4.2.1. Participant characteristics

All studies (n=67) included adults with type 2 diabetes. A case definition of people with type 2 diabetes included in the trials are presented in table 2.2 (mean age, type 2 diabetes duration, and inclusion/exclusion criteria).

2.4.2.2. Psychological intervention and control group characteristics

The psychological interventions described in trials were categorised into three groups: cognitive behavioural therapy (n=22), counselling (n=44), and interpersonal psychotherapy (n=1). Through extracting additional information on behaviour change techniques, it was found cognitive behavioural therapy and counselling studies shared similar behaviour change techniques (table 2.3) including ‘goals and planning’ and ‘social support’. Zero behaviour change techniques were coded for the interpersonal psychotherapy study (Gois et al., 2014).

Psychological interventions were mainly delivered face-to-face (n=52), others were delivered via telephone (n=8), or face-to-face and telephone (n=7). The format of delivery was one-to-one (n=40), group (n=24) or family (n=3). The mean number of sessions was 7.39 (SD=4.81), mean duration of each session was 1.25 hours (SD=0.67), and the mean overall duration of intervention was 25.34 weeks (SD=26.95).

Psychological intervention facilitators included diabetes specialists (n=30, i.e. diabetes nurses [n=24], diabetologists [n=4], diabetes researchers [n=1], dieticians [n=1]), psychology professionals (n=23, i.e. counsellors [n=5], clinical psychologists [n=12], psychiatrist [n=2], IAPT practitioner [n=1], health psychologist [n=1], depression clinical specialist [n=1], psychology assistant [n=1]), and other (n=13, i.e. lifestyle facilitator [n=1], psychology researcher [n=5], peers [n=1], community health worker [n=3], medical assistant [n=1], music therapist [n=1], occupational therapist [n=1]).

Fidelity assessment of the psychological intervention treatment was present in 20 out of the 67 studies (table 2.1) via expert observation or assessment of audio-tape recordings of psychological interventions.

The frequency of studies per behaviour change technique category is presented in table 2.4. 'Covert learning' was the least common behaviour change technique and was not extracted from any of the included studies. Examples of the most frequently coded behaviour change technique included:

> *'Social support'* (n=52 studies) e.g. "Group motivational interviewing was the intervention used in the experimental group."(Momtazi, Salimi, Zenouzian, Shourani, & Urquhart, 2018)
>
> *'Goals and planning'* (n=51 studies) e.g. "…devising a specific action plan to implement the solution." (Rees et al., 2017)
>
> *'Feedback and monitoring'* (n=28 studies) e.g. "…given an accelerometer to wear for 1 week at baseline and again at 3-month follow up to measure physical activity."(Chlebowy et al., 2015)

Most psychological interventions described 1, 3, or 4 behaviour change techniques (figure 2.4). One study reported using 12 behaviour change techniques (De Greef, Deforche, Tudor-Locke, & De Bourdeaudhuij, 2010). One study did not have sufficient text to describe the intervention in detail and therefore no behaviour change techniques were extracted

(Gois et al., 2014). The mean frequency of behaviour change techniques per psychological intervention was 3.63 (SD=2.28).

Control groups were categorised into the following: usual care (n=45), attention control (n=17), waiting list control (n=4), and diabetes education (n=1).

2.4.2.3. Outcome characteristics

Trials reported HbA1c in % or mmol/mol. Mean HbA1c per study is reported in table 2.2. The mean follow-up time was 7.49 months (SD=4.19).

2.4.2.4. Publication characteristics

Included trials were published between 2004 and 2018. Trials were published in Europe (n=26), North America (n=23), Asia (n=12), Australia (n=4), and South America (n=2).

2.4.3. Risk of bias within studies

Most studies were rated unclear (n=35) and low (n=29) risk of bias, few were rated high risk of bias (n=3), table 2.1 (figure 2.5).

2.4.4. Results of individual studies and synthesis of results

A random-effects meta-analysis for all included trials (N=67) found HbA1c was significantly lower for people with type 2 diabetes receiving the psychological intervention condition compared with the control condition (SMD= -0.17, 95% CI= -0.24, -0.11, p<0.001), figure 2.6. Heterogeneity was moderate (I^2=64.6%, p<0.001).

2.4.4.1. Sub-analysis of HbA1c by psychological intervention category

A sub-group random-effects meta-analysis of HbA1c by psychological intervention category found there was significantly lower HbA1c for people with type 2 diabetes receiving both counselling (SMD=-0.18, 95% CI= -0.26, -0.11, p<0.001) and cognitive behavioural therapy (SMD= -0.16, 95% CI= -0.29, -0.04, p=0.009) compared with the control. A meta-regression found no difference in HbA1c effect size between counselling and cognitive behavioural therapy conditions (b=-0.17, 95% CI= -0.18, 0,15, p=0.84). There was moderate to high heterogeneity for both counselling (I^2=69.8%, p<0.001) and cognitive behavioural therapy groups (I^2=52.5%, p=0.002).

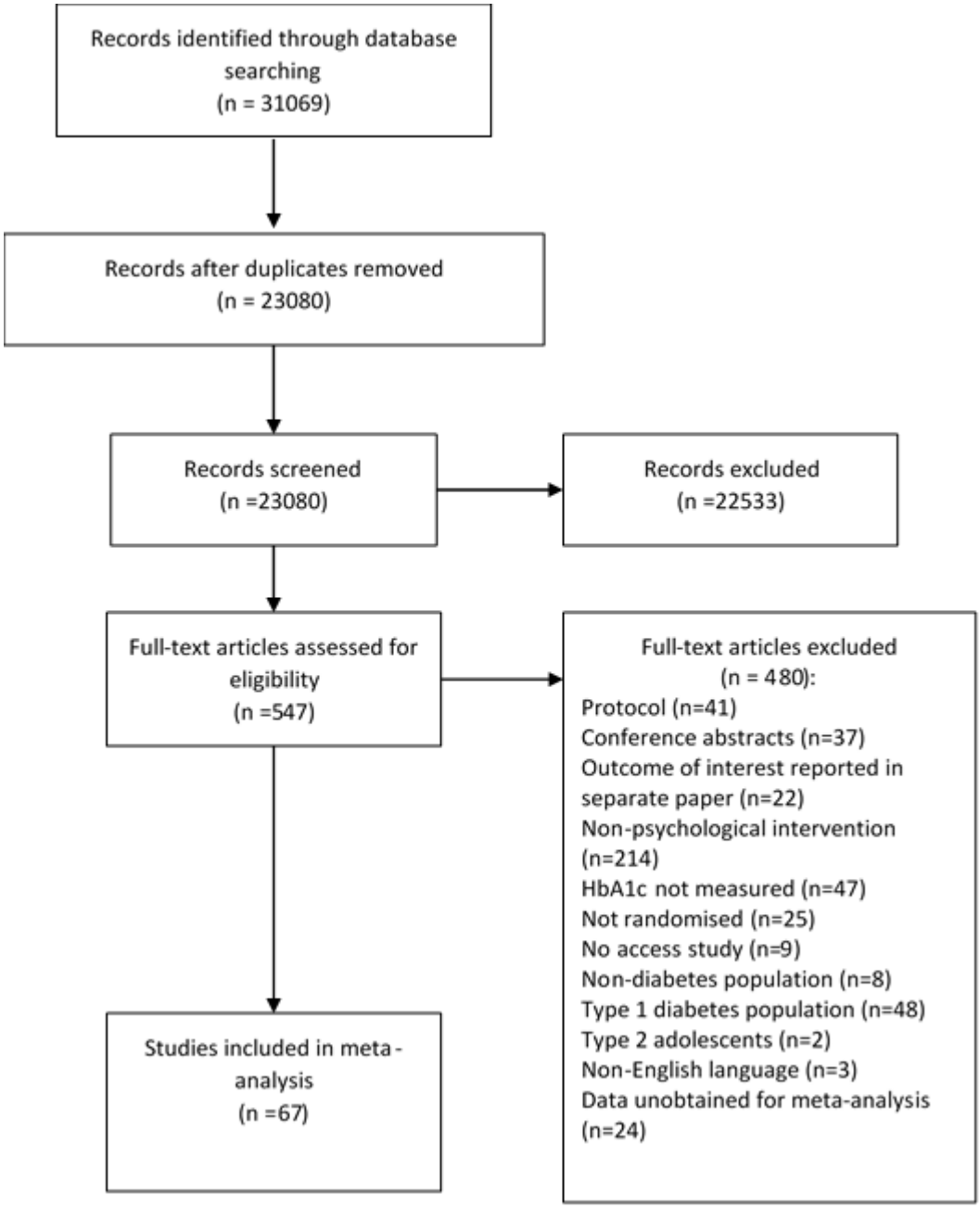

Figure 2.3-*Flow chart of studies in meta-analysis of psychological interventions for people with type 2 diabetes*

2.4.5. Risk of bias across studies

For all studies (N=67), according to Egger's test there was evidence of publication bias ($p<0.001$) but the trim and fill method identified no missing studies.

2.4.6. Additional analysis: Meta regression of behaviour change techniques

A meta-regression found no association between behaviour change technique category and HbA1c (b=-0.16 [95% CI= -0.25, -0.06], p=0.91). Though there were no significant differences in effect size between behaviour change technique categories, a sub-group meta-analysis found 6 behaviour change technique categories led to a significant reduction in HbA1c: 'goals and planning' (n=51, SMD=-0.15, $p<0.001$), 'feedback and monitoring' (n= 28, SMD=-0.24, $p<0.001$), 'social support' (n=52, SMD=-0.17, $p<0.001$), 'shaping knowledge' (n=17, SMD=-0.26, p=0.001), 'regulation' (n=20, SMD=-0.2, $p<0.001$), and 'identity' (n=13, SMD=-0.27, p=0.02), table 2.5.

A meta-regression found no association between presence of fidelity assessment and HbA1c (b=0.11 [95% CI=-0.04, 0.27], p=0.15). Meta-regressions found no association between frequency of behaviour change techniques per psychological intervention (b=-0.02 [95% CI=-0.05, 0.02], p=0.29), or year of publication (b=-0.01 [95% CI=-0.45, 0.42], p=0.44), and HbA1c.

Table 2.1-*Study characteristics of English language studies included in the meta-analysis of psychological interventions to improve HbA1c in type 2 diabetes*

Reference	Intervention name	Type of Psychological Intervention	Control group	Fidelity assessment	Risk of bias
(Akturan, Kaya, Ünalan, & Akman, 2017)	BATHE therapeutic interview technique	Counselling	Usual care	NR	High
(Balducci et al., 2017)	Physical activity counselling	Counselling	Usual care	NR	Low
(Browning et al., 2016)	Motivational interviewing	Counselling	Usual care	NR	Low
(Carrasquillo et al., 2017)	Community health worker intervention	Counselling	Enhanced usual care	Reported	Low
(Chee et al., 2017)	Structured lifestyle intervention	Counselling	Usual care	NR	Unclear
(Chen, Creedy, et al., 2012)	Motivational interviewing	Counselling	Diabetes education	NR	Unclear
(Chew, Vos, Stellato, Ismail, & Rutten, 2018)	Structured, value-based, emotion-focused educational programme (VEMOFIT)	Counselling	Attention control	NR	Low
(Chiu et al., 2016)	Minimal psychological intervention (MPI)	Counselling	Usual care	NR	Unclear
(Chlebowy et al., 2015)	Motivational interviewing	Counselling	Usual care	Reported	Unclear
(Chwastiak et al., 2017)	Community mental health care (CMHC)-based collaborative care model	Counselling	Usual care	NR	Unclear
(Dale, Caramlau, Sturt, Friede, & Walker, 2009)	Telephone peer-delivered intervention	Counselling	Usual care	NR	Unclear
(De Greef et al., 2010)	Cognitive-Behavioural Pedometer-based group intervention	CBT	Usual care	NR	Low
(De Greef, Deforche, Tudor-Locke, & De Bourdeaudhuij, 2011)	Pedometer-based physical activity intervention	Counselling	Usual care	NR	Low
(Döbler et al., 2018)	Post discharge telephone-delivered follow-up intervention	Counselling	Usual care	Reported	Low
(Eakin et al., 2014)	Telephone-delivered weight loss intervention	Counselling	Usual care	Reported	Unclear
(Egede, Williams, Voronca, Gebregziabher, & Lynch, 2017)	Behavioural activation treatment	CBT	Same-room treatment	Reported	Unclear
(Ell et al., 2011)	Multifaceted Diabetes and Depression Program	CBT	Enhanced usual care	NR	Unclear
(Evans, Lewin, Bowen, & Lowe, 2010)	Dealing with Anxiety CBT program	CBT	Waiting list control	NR	Low
(Fan et al., 2016)	Individualised diabetes education program	Counselling	Group education	NR	High
(Farmer et al., 2012)	Nurse-led consultation-based intervention	Counselling	Usual care	Reported	Unclear
(Furler et al., 2017)	The Stepping Up Model of care	Counselling	Usual care	NR	Low
(Garcia-Huidobro, Bittner, Brahm, & Puschel, 2011)	Innovative Care for Chronic Conditions Framework	Counselling	Usual care	NR	Low

Continued….

Reference	Intervention name	Type of Psychological Intervention	Control group	Fidelity assessment	Risk of bias
(Gois et al., 2014)	Interpersonal Psychotherapy	IPT	Pharmacological treatment	NR	Unclear
(Gomes et al., 2017)	Family social support in an education program	Counselling	Education	NR	Unclear
(Gregg, Callaghan, Hayes, & Glenn-Lawson, 2007)	Limited acceptance intervention	CBT	Education alone	NR	Low
(Griffin et al., 2014)	ADDITION-Plus	Counselling	Intensive treatment alone	Reported	Low
(Hartmann et al., 2012)	Mindfulness-Based Stress-Reduction Intervention	Counselling	Usual care	NR	Unclear
(Hawkins, 2010)	Videophone motivational interviewing diabetes self-management education	Counselling	Attentional control	Reported	Unclear
(Hermanns et al., 2015b)	Diabetes-Specific Cognitive Behavioural Treatment Program	CBT	Diabetes education	NR	Low
(Hermanns et al., 2017)	MEDIAS 2 BSC	Counselling	Diabetes education	NR	Low
(Huang et al., 2016)	Motivation enhancement therapy (MET) plus CBT	CBT	Usual care	NR	Unclear
(Ismail et al., 2018)	Diabetes-6 (D6) intervention	Counselling	Usual care	Reported	Unclear
(Jansink et al., 2013)	Comprehensive diabetes programme	Counselling	Usual care	NR	Low
(Jiang, Fan, Wu, Geng, & Hu, 2017)	Care intervention	Counselling	Usual care	NR	High
(Juul, Maindal, Zoffmann, Frydenberg, & Sandbaek, 2014a)	Training course for practice nurses	Counselling	Usual care	NR	Unclear
(Juul, Andersen, Arnoldsen, & Maindal, 2016)	Brief diabetes risk reduction intervention	Counselling	Usual care	NR	Unclear
(Kasteleyn, Vos, Rijken, Schellevis, & Rutten, 2016)	Tailored support	Counselling	Attentional control	NR	Unclear
(Keeratiyutawong, Hanucharurnkul, Melkus, Panpakdee, & Vorapongsathorn, 2006)	Self-management program	CBT	Diabetes education	NR	Unclear
(Keogh et al., 2011)	Psychological family-based intervention	Counselling	Usual care	NR	Unclear
(Kim et al., 2015a)	Community-Based Multi Modal Behavioural Self-Help Intervention (SHIP-DM)	Counselling	Education only	Reported	Unclear
(Lamers, Jonkers, Bosma, Knottnerus, & van Eijk, 2011)	Nurse-administered minimal psychological intervention (MPI)	CBT	Usual care	Reported	Low
(Li, Li, Shi, & Gao, 2014)	Motivational Interviewing (MI)	Counselling	Diabetes education	NR	Low

Continued….

Reference	Intervention name	Type of Psychological Intervention	Control group	Fidelity assessment	Risk of bias
(Mandel, Davis, & Secic, 2013)	Music Therapy (MT) and Music-Assisted Relaxation and Imagery (MARI)	CBT	Diabetes education	Reported	Low
(D'Eramo Melkus et al., 2010)	Diabetes education, Coping skills training, Care intervention	CBT	Usual care	Reported	Unclear
(Momtazi et al., 2018)	Group motivational interviewing	Counselling	Wait-list control	NR	Unclear
(Osborn et al., 2010b)	Brief culturally tailored diabetes intervention	Counselling	Usual care	NR	Unclear
(Penckofer et al., 2012)	The Study of Women's Emotions and Evaluation of a Psychoeducational (SWEEP) Program	CBT	Usual care	Reported	Unclear
(Petrak, 2015)	CBT vs. Sertraline	CBT	Sertraline treatment + usual care	NR	Low
(Pibernik-Okanović, 2015)	Psychoeducational course and physical activity intervention	CBT	Enhanced usual care	NR	Low
(Piette et al., 2011)	Telephone-delivered CBT program	CBT	Enhanced usual care	Reported	Unclear
(Pladevall, Divine, Wells, Resnicow, & Williams, 2015)	The Multi-Arm Intervention Diabetes Adherence Study	Counselling	Usual care	Reported	Low
(Plotnikoff et al., 2013)	The Alberta Diabetes and Physical Activity Trial (ADAPT)	Counselling	Physical activity education materials	NR	Low
(Rees et al., 2017)	Problem-Solving Therapy for Primary Care (PST-PC)	CBT	Usual care	NR	Unclear
(Sacco, 2009)	Brief, regular, telephone-delivered lifestyle modification program	Counselling	Usual care	NR	Unclear
(Safren et al., 2014)	CBT for Adherence and Depression (CBT-AD)	CBT	Enhanced usual care	NR	Unclear
(Shayeghian, Hassanabadi, Aguilar-Vafaie, Amiri, & Besharat, 2016)	Group based acceptance and commitment therapy (ACT)	CBT	Education with routine treatment	NR	Unclear
(Siebolds, Gaedeke, & Schwedes, 2006)	Self-monitoring of blood glucose intervention	Counselling	Non-standardised counselling	NR	Low
(Steed, Barnard, Hurel, Jenkins, & Newman, 2014)	University College London-Diabetes Self-management Programme (UCL-DSMP)	Counselling	Usual care	NR	Unclear
(van Son, Nyklicek, et al., 2014)	Mindfulness-based cognitive therapy (MBCT)	CBT	Usual care	NR	Low
(Wagner et al., 2016)	Stress management intervention	Counselling	Diabetes education;	Reported	Unclear

Continued….

Reference	Intervention name	Type of Psychological Intervention	Control group	Fidelity assessment	Risk of bias
(Welch, Zagarins, Feinberg, & Garb, 2011)	Brief diabetes self-management education intervention (DSME)	Counselling	Diabetes self-management education	Reported	Unclear
(Welschen et al., 2013)	CBT	CBT	Usual care	Reported	Low
(West, DiLillo, Bursac, Gore, & Greene, 2007)	Behavioural obesity treatment program with motivational interviewing	Counselling	Attention control	Reported	Low
(Whittemore, Melkus, Sullivan, & Grey, 2004)	Multifaceted nurse-coaching intervention	Counselling	Usual care	NR	Low
(Williams et al., 2004)	The Improving Mood–Promoting Access to Collaborative Treatment (IMPACT)	CBT	Usual care	NR	Low
(Wolever et al., 2010)	Integrative health (IH) coaching	Counselling	Usual care	NR	Low
(Wroe, Rennie, Sollesse, Chapman, & Hassy, 2018)	Modified group intervention	CBT	Usual care	NR	Unclear

*CBT=cognitive behavioural therapy; NR= not reported

Table 2.2- *Case definition of participants included in a meta-analysis of psychological interventions to improve HbA1c in type 2 diabetes*

Reference	Year, country	Mean age (SD or range), years intervention group	Mean age (SD or range), years control group	Mean (SD or range) duration of diabetes, years intervention group	Mean (SD or range) duration of diabetes, years control group	Mean (SD) baseline HbA1c intervention group	Mean (SD) baseline HbA1c control group	Age inclusion criteria (years)	Diabetes duration inclusion criteria (months)	HbA1c inclusion criteria
(Akturan et al., 2017)	2017, Turkey	57·51 (7.0)	56·33 (7·56)	NR	NR	7.48% (1.49)	7.39% (1.28)	18-80	≥6	None
(Balducci et al., 2017)	2017, Italy	NR	NR	NR	NR	7.43% (1.60)	7.32% (1.37)	40-80	≥12	None
(Browning et al., 2016)	2016, China	63·7 (7·6)	64.0 (9.0)	10.0 (6·5)	9·6 (6·6)	10.60% (2.09)	10.29% (1.71)	≥50	None	None
(Carrasquillo et al., 2017)	2017, USA	55·3 (7·1)	55·2 (6·1)	11·7 (8·2)	11·2 (8·4)	9.3% (2.1)	9.3% (1.9)	18-65	≥6	8% or more
(Chee et al., 2017)	2017, Malaysia	NR	NR	NR	NR	I1: 7.7% (1.1) I2: 7.7% (1.4)	7.9% (1.3)	30-65	None	7-11%
(Chen, Creedy, et al., 2012)	2012, Taiwan	59·19 (10·24)	58·67 (10·23)	7·98 (7·57)	7·91 (6·95)	8.92% (2.17)	8.52% (1.82)	>18	>3	None
(Chew et al., 2018)	2018, Malaysia	55·6 (10·8)	55·8 (8·8)	NR	NR	9.9% (1.8)	9.5% (2.1)	≥18	≥24	8% or more
(Chiu et al., 2016)	2016, Taiwan	64·78 (0·3)	64·59 (0·4)	10.0 (0·6)	10·58 (0·2)	7.6% (1.5)	7.7% (1.3)	≥50	None	None
(Chlebowy et al., 2015)	2015, USA	55·8 (2·1)	53 (2·25)	NR	NR	7.8% (0.16)	8.1% (0.18)	≥18	None	None
(Chwastiak et al., 2017)	2018, USA	NR	NR	NR	NR	9.4% (2.2)	8.3% (1.9)	18-64	≥6	8% or more
(Dale et al., 2009)	2009, UK	NR	NR	NR	NR	1) 8.9% (1.5) 2) 8.4% (1.1)	8.7% (1.3)	≥18	None	>7.4%
(De Greef et al., 2010)	2010, Belgium	NR	NR	NR	NR	7.5% (1.1)	8.0% (1.3)	35-75	≥6	None
(De Greef et al., 2011)	2011, Belgium	I1: 70 (6·3) I2: 66·6 (9·5)	66 (11·1)	NR	NR	I1: 7.23% (0.71) I2: 7.12% (1.35)	7.0 (0.87)	<80	≥6	<12%
(Döbler et al., 2018)	2018, Germany	51·6 (5·7)	52·2 (5·4)	8·7 (6·6)	9·6 (5·9)	7.8% (1.7)	7.6% (1.4)	18-70	None	None

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Reference	Year, country	Mean age (SD or range), years intervention group	Mean age (SD or range), years control group	Mean (SD or range) duration of diabetes, years intervention group	Mean (SD or range) duration of diabetes, years control group	Mean (SD) baseline HbA1c intervention group	Mean (SD) baseline HbA1c control group	Age inclusion criteria (years)	Diabetes duration inclusion criteria (months)	HbA1c inclusion criteria
(Eakin et al., 2014)	2014, Australia	57·7 (8·1)	58·3 (9·0)	NR	NR	Median: 7.6% (6.3, 8.5)	Median: 7.0% (6.4, 7.9)	20-75	None	None
(Egede et al., 2017)	2017, USA	62·7 (3·4)	63·5 (4·9)	NR	NR	7.35%	6.90%	≥58	None	None
(Ell et al., 2011)	2011, USA	All: 54 (8·7)	All: 54 (8·7)	NR	NR	9.03% (2.23)	9.13% (2.21)	≥18	None	None
(Evans, Lewin, et al., 2010)	2010, Australia	All: 57·1(22-84)	All: 57·1(22-84)	All: 14·3(1-45)	All: 14·3(1-45)	8.33% (1.44)	7.41 (1.64)	≥18	None	None
(Fan et al., 2016)	2016, China	62·94 (10·72)	64·89 (10·14)	11·4 (4·8)	11·6 (5·0)	9.61% (1.92)	9.80% (1.98)	None	None	None
(Farmer et al., 2012)	2012, UK	62·5 (11.0)	64·1 (10·3)	6·7 (4·8)	6·9 (5·3)	8.37% (1.25)	8.28% (1.22)	≥18	≥3	7.5% or more
(Furler et al., 2017)	2017, Australia	61·7 (9·7)	62·0 (10·6)	NR	NR	8.7% (8.1-9.7)	8.5% (8-9.6)	<80	None	7.5% or more
(Garcia-Huidobro et al., 2011)	2011, Chile	53·4 (8·1)	53·5 (9·8)	NR	NR	10.3% (2.0)	9.5% (2.2)	18-70	None	7% or more
(Gois et al., 2014)	2014, Portugal	56·82 (4·25)	53·81 (7·04)	13·12 (4·85)	11·63 (6·68)	9.36% (2.38)	8.76% (1.94)	18-65	>6	None
(Gomes et al., 2017)	2017, Brazil	NR	NR	NR	NR	9.47% (2.01)	9.40% (2.00)	≥40	None	None
(Gregg et al., 2007)	2007, USA	49·8	49.8	5·3	6·6	8.17% (1.86)	8.21% (1.91)	≥18	None	None
(Griffin et al., 2014)	2014, UK	59·5 (7·5)	59·8 (7·5)	NR	NR	7.23% (1.62)	7.01% (1.23)	40-69	< 36	None
(Hartmann et al., 2012)	2012, Germany	58·7 (7·4)	59·3 (7·8)	11.0 (7·5)	12·2 (7·6)	7.26% (1.08)	7.27% (1.06)	30-70	<36	None
(Hawkins, 2010)	2010, USA	64	65·8 (10·4)	NR	NR	9.0% (2.3)	8.9% (3.1)	≥60	None	7% or more
(Hermanns et al., 2015b)	2015, Germany	34·2 (14·9)	43·4 (13·8)	14·2 (10·3)	14·2 (10·7)	8.9% (1.8)	8.9% (1.8)	18-70	None	None
(Hermanns et al., 2017)	2017, Germany	NR	NR	NR	NR	8.0% (1.3)	7.9% (1.2)	18-75	None	None
(Huang et al., 2016)	2016, Taiwan	55·06 (10·44)	57·83 (10·38)	In months: 44·32 (21·59)	In months: 45·7 (18·06)	7.68% (1.44)	7.84% (1.95)	≥20	None	None
(Ismail et al., 2018)	2018, UK	59 (11·1)	58·9 (11·4)	10.0 (7-13)	9.0 (5-12)	81.0 mmol/mol (17.1)	80.1 mmol/mol (19.1)	18-79	≥24	8% or more
(Jansink et al., 2013)	2013, Netherlands	64·1 (8·9)	63·9 (9·8)	7·5 (6·0)	7·8 (5·8)	7.8% (0.9)	7.7% (0.7)	<80	None	7% or more

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Reference	Year, country	Mean age (SD or range), years intervention group	Mean age (SD or range), years control group	Mean (SD or range) duration of diabetes, years intervention group	Mean (SD or range) duration of diabetes, years control group	Mean (SD) baseline HbA1c intervention group	Mean (SD) baseline HbA1c control group	Age inclusion criteria (years)	Diabetes duration inclusion criteria (months)	HbA1c inclusion criteria
(Jiang et al., 2017)	2017, China	56·3 (5·3)	57·1 (5·5)	1·24 (0·38)	1·27 (0·36)	7.7% (0.9)	8.3% (1.1)	18-70	None	None
(Juul et al., 2014a)	2014, Denmark	60·2 (8·2)	60·7 (8·6)	8 (4-14)	8 (4-15)	7.1% (1.3)	7.1% (1.3)	40-74	None	None
(Juul et al., 2016)	2016, Denmark	Median: 58 (50, 63)	Median: 60 (51, 64)	NR	NR	40.7 mmol/mol (3.5)	40.6 mmol/mol (3.9)	<70	None	6-6.4%
(Kasteleyn et al., 2016)	2016, Netherlands	66.0 (9·3)	65·6 (9·4)	7.0 (2·8-16)	8·5 (5-15)	7.2% (3.5)	6.8% (3.1)	>35	>12	None
(Keeratiyutawong et al., 2006)	2006, Thailand	NR	NR	NR	NR	8.93% (2.4)	7.89% (1.8)	21-60	<120	None
(Keogh et al., 2011)	2011, Ireland	59·96 (11·67)	57·29 (11·34)	9·17(7·1)	9·65 (6·45)	Median: 9.06 (0.96)	Median: 9.29 (1.13)	>18	>12	8% or more
(Kim et al., 2015a)	2015, USA	59·1 (8·4)	58·3 (8·5)	In months: 105·3 (87·6)	In months: 99·3 (84·8)	8.9% (2.05)	8.8% (3.06)	≥35	None	7% or more
(Lamers et al., 2011)	2011, Netherlands	70·7 (6·6)	69·7 (6·6)	8·2 (8·8)	9·8 (9·1)	7.5% (1.1)	7.2% (1.4)	≥60	None	None
(Li et al., 2014)	2014, China	58·5 (5.0)	59·2 (5·2)	1·3 (0·5)	1·2 (0·4)	10.1% (2.7)	9.7% (3.5)	40-70	12-24	9% or more
(Mandel et al., 2013)	2013, USA	58 (11·29)	C1: 57·1 (9·67) C2: 58·9 (10·76)	3·22 (5·94)	C1: 2·32 (6·1) C2: 3·78 (7·06)	7.7% (1.81)	C1: 7.4% (1.56) C2: 7.6% (1.48)	30-85	None	None
(D'Eramo Melkus et al., 2010)	2010, USA	47.0 (9.0)	45.0 (10.0)	NR	NR	8.0% (2.1)	8.3% (2.2)	21-65	None	None
(Momtazi et al., 2018)	2018, Iran	NR	NR	NR	NR	8.23% (1.10)	7.98% (0.80)	30-60	None	7% or more
(Osborn et al., 2010b)	2010, USA	56·9 (11·3)	58·4 (10·1)	13·2 (12)	12·3 (9·4)	7.8% (1.4)	7.3% (1.6)	≥18	≥12	None

Continued….

Reference	Year, country	Mean age (SD or range), years intervention group	Mean age (SD or range), years control group	Mean (SD or range) duration of diabetes, years intervention group	Mean (SD or range) duration of diabetes, years control group	Mean (SD) baseline HbA1c intervention group	Mean (SD) baseline HbA1c control group	Age inclusion criteria (years)	Diabetes duration inclusion criteria (months)	HbA1c inclusion criteria
(Penckofer et al., 2012)	2012, USA	54·8 (8·8)	54 (8·4)	10·5 (8·2)	10 (6·5)	7.8% (1.8)	7.9% (2.0)	≥18	≥6	None
(Petrak, 2015)	2015, Germany	49 (10·6)	47·9 (12·8)	15·7 (10·4)	15·0 (10·6)	9.30% (1.49)	9.20% (1.44)	21-69	None	7.5% or more
(Pibernik-Okanović, 2015)	2015, Croatia	57·7 (6·2)	58·2 (5·6)	11·4 (9·1)	10·5 (6·9)	7.4% (1.2)	7.2% (1.1)	18-65	≥12	None
(Piette et al., 2011)	2011, USA	55·1 (9·4)	56 (10·9)	NR	NR	7.5% (1.7)	7.7% (1.7)	≥21	None	None
(Pladevall et al., 2015)	2015, USA	64·5 (10·5)	C1: 64·9 (11·5) C2: 63·3 (10·9)	NR	NR	8.0% (1.3)	C1: 8.2% (1.4) C2: 8.0% (1.4)	≥18	None	7% or more
(Plotnikoff et al., 2013)	2013, Canada	62·3 (11·1)	C1: 61.0 (11·7) C2: 61·4 (12·6)	8·8 (7.0)	C1: 11·7 (9·9) C2: 10·7 (9·9)	7.08% (1.3)	C1: 7.06% (1.9) C2: 7.24% (0.12)	≥18	None	None
(Rees et al., 2017)	2017, Australia	60·1 (7.0)	58·6 (8·8)	17·5 (10)	23.0 (15.0)	8.2% (1.57)	8.1% (1.2)	None	None	None
(Sacco, 2009)	2009, USA	All: 52(8·6)	All: 52(8·6)	All: 9·5 (7·2)	All: 9·5 (7·2)	8.4% (1.37)	8.5% (2.01)	18-65	None	None
(Safren et al., 2014)	2014, USA	55·44 (8·72)	58·31 (7·41)	NR	NR	8.81% (1.78)	8.74% (1.41)	18-70	None	7% or more
(Shayeghian et al., 2016)	2016, Iran	55·18 (8·26)	55·70 (8·98)	4·9 (1·40)	4·54 (1·54)	7.46% (1.66)	7.61% (1.38)	40-60	12-120	None
(Siebolds et al., 2006)	2006, Germany	58·7 (7·6)	60·5 (6·6)	65·5 (months; 57·2)	62·6 (months; 47·3)	8.47% (0.86)	8.35% (0.75)	≥18	None	None
(Steed et al., 2014)	2014, UK	59·2 (8·8)	60·3 (8·6)	10·7 (7·5)	10·9 (7·9)	8.2% (1.3)	8.6% (1.8)	< 75	None	None
(van Son, Nyklicek, et al., 2014)	2014, Netherlands	56.0 (13.0)	57.0 (13.0)	NR	NR	7.5% (1.2)	7.6% (1.2)	18-80	None	None
(Wagner et al., 2016)	2016, USA	60.0 (11·2)	60·8 (12·1)	NR	NR	8.5% (1.4)	8.6% (1.9)	≥18	≥6	7% or more
(Welch et al., 2011)	2011, USA	I1: 56·1 (10·4) I2: 54·9 (9·3)	C1: 57·2 (10·9) C2: 54·4 (10·3)	I1: 9·8 (8) I2: 9 (7·3)	C1: 7 (6·5) C2: 7·1 (5·8)	I1: 9.1 (1.5) I2: 8.8 (1.0)	C1: 8.8 (1.3) C2: 8.9 (1.2)	30-70	None	7.5% or more

(Welschen et al., 2013)	2013, Netherlands	60·5 (9·4)	61·2 (8·8)	7·6 (5)	7·8 (6·1)	6.8% (1.0)	6.7% (1.0)	18-75	None	7% or more
Continued…										
Reference	**Year, country**	**Mean age (SD or range), years intervention group**	**Mean age (SD or range), years control group**	**Mean (SD or range) duration of diabetes, years intervention group**	**Mean (SD or range) duration of diabetes, years control group**	**Mean (SD) baseline HbA1c intervention group**	**Mean (SD) baseline HbA1c control group**	**Age inclusion criteria (years)**	**Diabetes duration inclusion criteria (months)**	**HbA1c inclusion criteria**
(West et al., 2007)	2007, USA	54.0 (10.0)	52.0 (10.0)	5·8 (6·5)	4·9 (5.0)	7.54% (1.4)	7.62% (1.4)	≥18	None	None
(Whittemore et al., 2004)	2004, USA	All: 57·6 (10·9)	All: 57·6 (10·9)	All: 2·7 (3·0)	All: 2·7 (3·0)	7.7% (1.00)	7.6% (1.00)	30-70	None	7% or more
(Williams et al., 2004)	2004, USA	70·1 (6·9)	70·3 (7·1)	NR	NR	7.26% (1.32)	7.30% (1.43)	≥60	None	None
(Wolever et al., 2010)	2010, USA	53·1 (8·29)	52·8(7·64)	11·8 (8·5)	10·6 (6·43)	7.7% (1.94)	8.2% (1.89)	≥18	≥12	None
(Wroe et al., 2018)	2018, UK	63·48 (11·04)	63·63 (10·71)	NR	NR	67.12 mmol/mol (21.02)	61.86 mmol/mol (14.29)	None	None	None

Table 2.3- *Number of counselling and cognitive behavioural therapy studies which included each behaviour change technique category*

Behaviour change technique category	Number of counselling studies which included each behaviour change technique category	Number of cognitive behavioural therapy studies which included each behaviour change technique category
1. Goals and planning	31	15
2. Feedback and monitoring	20	7
3. Social support	36	14
4. Shaping knowledge	13	4
5. Natural consequences	2	2
6. Comparison of behaviour	7	4
7. Associations	1	2
8. Repetition and substitution	9	2
9. Comparison of outcomes	7	3
10. Reward and threat	5	2
11. Regulation	7	11
12. Antecedents	5	3
13. Identity	8	6
14. Scheduled consequences	1	1
15. Self-belief	2	0
16. Covert learning	0	0

Table 2.4- *Frequency of studies per behaviour change technique category*

Behaviour change technique category	Number of studies behaviour change techniques are present
1. Goals and planning	51
2. Feedback and monitoring	28
3. Social support	52
4. Shaping knowledge	17
5. Natural consequences	4
6. Comparison of behaviour	11
7. Associations	3
8. Repetition and substitution	11
9. Comparison of outcomes	10
10. Reward and threat	8
11. Regulation	20
12. Antecedents	8
13. Identity	13
14. Scheduled consequences	2
15. Self-belief	2
16. Covert learning	0

Table 2.5- *Standardised mean difference in HbA1c per behaviour change technique category*

Behaviour change technique category	**Overall SMD**	**p-value**	**95% CI**
1. Goals & planning	-0.15	<0.001***	-0.23, -0.08
2. Feedback & monitoring	-0.24	<0.001***	-0.36, -0.12
3. Social support	-0.17	<0.001***	-0.23, -0.12
4. Shaping knowledge	-0.26	0.001**	-0.43, -0.11
6. Comparison of behaviour	-0.26	0.05	-0.50, 0.004
8. Repetition and substitution	-0.15	0.18	-0.38, 0.07
9. Comparison of outcomes	-0.19	0.05	-0.38, -0.004
10. Reward and threat	-0.05	0.61	-0.23, 0.14
11. Regulation	-0.2	<0.001***	-0.32, -0.08
12. Antecedents	-0.29	0.1	-0.63, 0.05
13. Identity	-0.27	0.02*	-0.50, -0.05

*Significant difference *P < 0.05*; ***P < 0.01*; ****P < 0.001*

Behaviour change techniques categories	Jiang et al. (2017)	Momtazi et al. (2018)	Rees et al. (2017)	Huang at al. (2016)	Penckofer et al. (2012)	Lamers et al. (2011)	Chlebowy et al. (2015)	Siebolds et al. (2006)	Safren et al. (2014)	Dobler et al. (2018)	Hawkins et al. (2010)	Petrak et al. (2015)	Chee et al. (2017)	Furler et al. (2017)	Shayeghian et al. (2016)	Chwastiak et al. (2018)	Chen et al. (2012)	Hartnamnn et al. (2012)	Keeratiyutawong et al. (2006)	Wolever et al. (2010)	Gregg et al. (2007)	Carrasquillo et al. (2017)	Kim et al. (2015)	Fan et al. (2016)	Wroe et al. (2018)	Jansink et al. (2013)	Hermanns et al. (2017)	Balducci et al. (2017)	Sacco et al. (2009)	van Son et al. (2014)	Li et al. (2014)	Griffin et al. (2014)	Akturan et al. (2017)
1. Goals and planning	■		■	■	■	■		■	■	■	■	■		■	■				■	■			■		■		■	■	■	■	■	■
2. Feedback and monitoring	■				■	■	■	■	■	■		■	■										■	■			■	■	■		■	■	
3. Social support		■		■	■	■	■	■	■	■	■	■	■	■		■	■		■	■		■	■	■		■	■		■	■	■	■	■
4. Shaping knowledge	■							■	■					■	■								■				■	■			■	■	
5. Natural consequences																								■									
6. Comparison of behaviour	■							■							■														■		■		
7. Associations									■																								
8. Repetition and substitution	■																												■		■	■	
9. Comparison of outcomes							■		■					■					■					■									
10. Reward and threat																			■										■		■		
11. Regulation				■	■				■			■	■		■			■	■	■	■				■								
12. Antecedents	■				■									■									■										
13. Identity	■				■				■			■							■				■		■								
14. Scheduled consequences																																	
15. Self-belief		■											■																				
16. Covert learning																																	
Frequency of behaviour change techniques per study	7	2	1	3	6	6	3	5	8	3	3	5	4	5	4	1	1	1	6	3	1	1	6	4	3	1	4	5	4	6	4	4	2

Continued….	Keogh et al. (2011)	Gomes et al. (2017)	Osborn et al. (2010)	Welschen et al. (2013)	Whittemore et (2004)	De Greef et al. (2011)	Pladevall et al. (2015)	Pibernik-Okanović et al. (2015)	Dale et al. (2009)	Steed et al. (2014)	Browning et al. (2016)	Kasteleyn et al. (2016)	Gois et al. (2014)	Chew et al. (2018)	Ismail et al. (2018)	Eakin et al. (2014)	Juul et al. (2014)	Hermanns et al. (2015)	Evans et al. (2010)	Ell et al. (2011)	Williams et al. (2004)	Plotnikoff et al. (2013)	Farmer et al. (2012)	Chiu et al. (2016)	Melkus et al. (2010)	Piette et al. (2011)	West et al. (2007)	Juul et al. (2016)	Mandel et al. (2013)	Welch et al. (2011)	Egede et al. (2017)	Wagner et al. (2016)	De Greef et al. (2010)	Garcia-Huidobro et al. (2011)
1. Goals and planning	■		■	■	■	■		■		■	■	■		■	■	■	■	■		■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
2. Feedback and monitoring			■		■	■						■		■		■						■		■		■	■				■		■	
3. Social support	■	■	■	■	■			■	■	■	■	■		■	■	■	■	■	■	■		■			■	■	■			■		■	■	■
4. Shaping knowledge			■			■				■	■			■																		■	■	
5. Natural consequences			■																														■	
6. Comparison of behaviour			■					■		■				■																		■	■	
7. Associations						■																											■	
8. Repetition and substitution			■			■								■		■											■					■	■	
9. Comparison of outcomes						■				■													■							■			■	
10. Reward and threat		■	■		■																											■	■
11. Regulation								■						■				■		■				■	■						■			
12. Antecedents																						■			■	■						■		
13. Identity	■		■			■						■															■					■	■	
14. Scheduled consequences						■																											■	
15. Self-belief																																		
16. Covert learning																																		
Frequency of behaviour change techniques per study	3	2	9	2	4	8	1	4	1	5	3	4	0	7	2	4	2	3	1	3	1	4	2	2	5	4	5	1	1	3	3	7	12	3

Figure 2.4- *Behaviour change technique category included in psychological interventions of studies in meta-analysis* in study 1

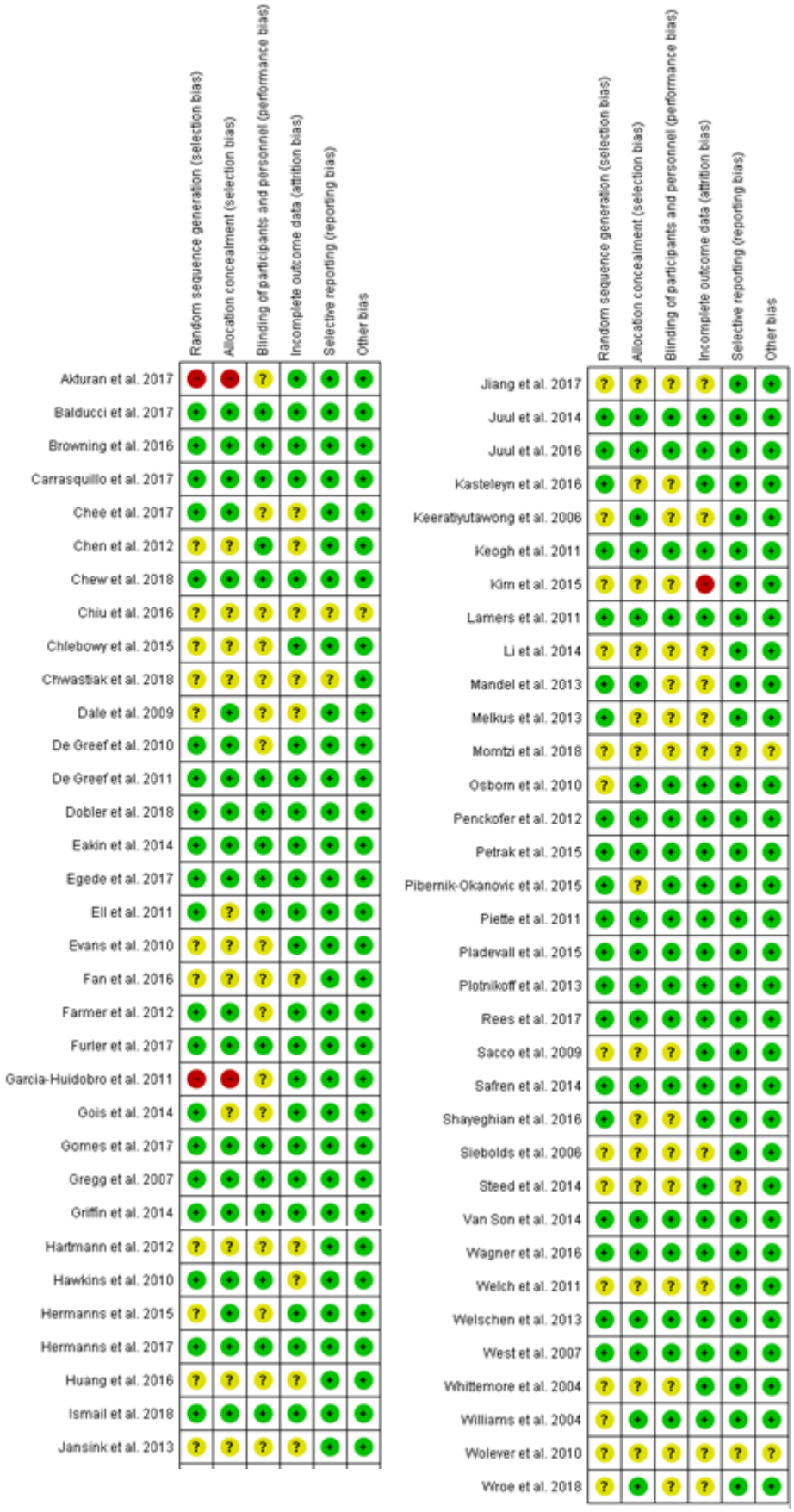

Figure 2.5-*Risk of bias assessment per study in a meta-analysis of psychological interventions to improve HbA1c in type 2 diabetes*

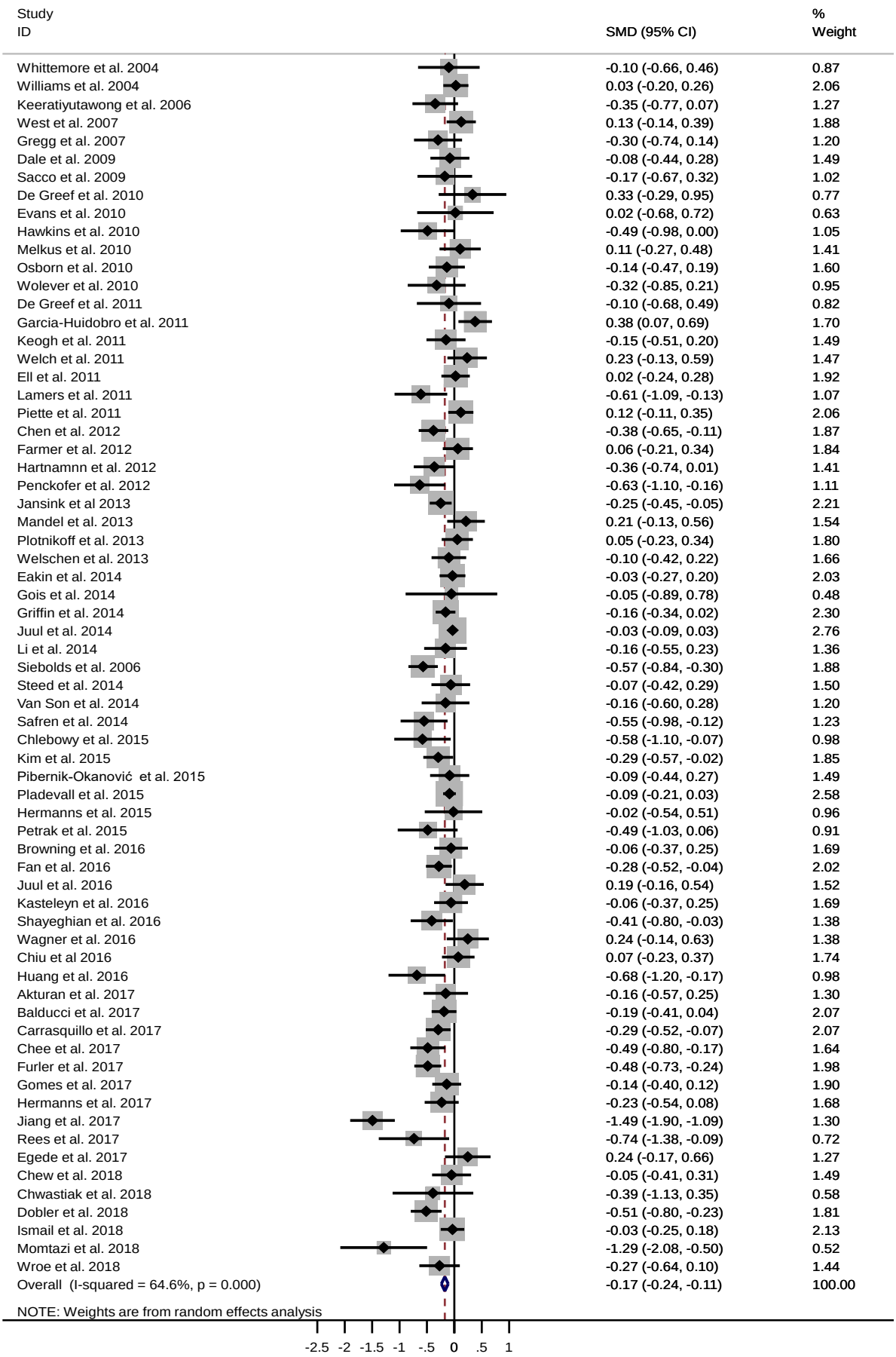

Figure 2.6-*A forest plot of a meta-analysis of psychological interventions to improve HbA1c in type 2 diabetes*

2.5. Discussion

2.5.1. Summary of evidence

The overall meta-analysis found a significant improvement in HbA1c for people with type 2 diabetes who received a psychological intervention versus the control group. Behaviour change techniques which were most commonly reported in the psychological interventions descriptions of trials included 'social support', 'goals and planning' and feedback and monitoring'. Behaviour change techniques which most commonly underpinned cognitive behavioural therapy and counselling psychological interventions included 'goals and planning' and 'social support'. This may account for why no differences in HbA1c improvement were found between cognitive behavioural therapy and counselling interventions.

Study 1 of this thesis found no significant differences in effect sizes between behaviour change technique categories and HbA1c. Therefore, it cannot be determined from this analysis which behaviour change technique categories are significantly better at improving HbA1c in type 2 diabetes. Even though there were no significant differences between them, behaviour change technique categories which were associated with a significant reduction in HbA1c included 'goals and planning', 'feedback and monitoring', 'social support', 'shaping knowledge', 'regulation', and 'identity'. This relates to other research into type 2 diabetes and effectiveness of behaviour change techniques which have similarly found improved outcomes using 'goals and planning' (Cradock et al., 2017; Hankonen et al., 2014; van Vugt et al., 2013), 'feedback and monitoring' (van Vugt et al., 2013), 'social support' (Presseau et al., 2015), and 'shaping knowledge' (Cradock et al., 2017). However, these studies did not investigate the association between psychological interventions and HbA1c, hence making these findings novel.

This study identified the mean number of behaviour change techniques per psychological intervention as 3.63. There was no association between frequency of behaviour change techniques per psychological intervention and HbA1c, therefore the optimal number of behaviour change techniques which improve HbA1c cannot be determined. This is a similar finding to a meta-regression in a study of behavioural interventions for obese adults where more behaviour change techniques were not associated with better outcomes (Dombrowski et al., 2012). On the contrary, findings from another type 2 diabetes study reported that the more behaviour change techniques used, the better the outcomes (Avery et al., 2012; Hankonen et al., 2014). In the analysis of this thesis, the trial which reported the highest number of behaviour change techniques did not have the largest

effect size in improving HbA1c (De Greef et al., 2010). In addition, the trial which reported the least behaviour change techniques did not have the smallest effect size in improving HbA1c (Gois et al., 2014). Again, supporting no association between frequency of behaviour change techniques and HbA1c.

Since the Behaviour Change Wheel and BCTTv1 were introduced almost 10 and 5 years ago, respectively, the reporting of specific techniques underpinning interventions should have improved (Michie et al., 2011; Michie et al., 2015). However, during data extraction of study 1 of this thesis, psychological intervention descriptions were unclear. It is possible that not all relevant behaviour change techniques were extracted due to lack of reporting. In addition, less than a third of studies reported fidelity assessment and therefore are unable to determine whether intervention facilitators were competent at delivering behaviour change techniques or whether behaviour change techniques were delivered as intended. Other systematic reviews also report poor reporting of fidelity assessment (Ekong & Kavookjian, 2016; Walton, Spector, Tombor, & Michie, 2017). For one nurse-led diabetes study which did assess fidelity (Ismail et al., 2018), it was found that some psychological techniques were delivered in the control condition (Magill et al., 2018), indicating contamination of skills can be an issue with randomised controlled trial results and subsequent interpretation. This also highlights the importance of fidelity assessment, so it is known which skills were delivered in the study conditions.

2.5.2. Strengths and limitations

A strength of this thesis chapter is, by identifying which smaller components of psychological interventions (behaviour change techniques) improve HbA1c, this ensures the future development of psychological interventions for people with type 2 diabetes is more likely to be successful in improving HbA1c. Another strength is at least two researchers were involved across the research process with high levels inter-reliability indicating consistency in screening full-text papers and coding behaviour change techniques. Therefore, there is confidence that other researchers could replicate these methods and obtain similar results.

Non-English language studies were excluded for this analysis owing to difficulties recruiting and training translators in BCTTv1, however, the overall effect size for HbA1c did not differ between this sample (n=67) and the overall sample (n=70). This analysis did not code which behaviour change techniques underpinned the control groups in the randomised controlled trials. Most studies reported usual care as the control condition with a limited description of what this entailed; therefore, behaviour change technique coding would not have been

possible in most cases. This study focused on HbA1c as an outcome, analysis of psychological (depression, diabetes distress) or self-management (dietary, medication adherence etc.) outcomes may have yielded different results.

Multiple factors could account for significant improvements in HbA1c for people with type 2 diabetes who have received a psychological intervention. Randomised controlled trials did not test behaviour change techniques or other active ingredients in isolation and pooling these studies for meta-analysis does not control for confounders. In addition, the analysis of this thesis chapter only reports the impact of individual behaviour change techniques on glycaemic levels. Therefore, without controlling for confounders or evaluating key combinations of behaviour change techniques, it is uncertain which specific combination of active ingredients lead to improvements in glycaemic levels. Improved reporting of active ingredients and the development of more sophisticated meta-analytic methods may help identify which intervention components are truly associated with specific outcomes (Dombrowski et al., 2012).

2.5.3. Conclusions

This analysis was the first to determine which behaviour change techniques underpin psychological interventions targeting HbA1c for people with type 2 diabetes. It was not possible to identify the most effective behaviour change techniques nor the optimal number of behaviour change techniques to improve HbA1c. However, the most frequently used behaviour change techniques which were associated with statistically significant improvements in HbA1c included: 'social support', 'goals and planning', and 'feedback and monitoring.' Future research to develop psychological interventions for people with type 2 diabetes should define behaviour change techniques in the psychological intervention design process, conduct fidelity assessment of interventionists, process evaluation of behaviour change techniques, and ensure consistent reporting of behaviour change techniques. These steps would help to identify the specific active ingredients of a successful psychological intervention to improve HbA1c for people with type 2 diabetes.

2.6. Chapter summary

Study 1 described in this chapter provides a foundation for which behaviour change techniques are most useful for DIME development. After extracting data from 67 studies, this study highlights the importance of reporting specific behaviour change techniques and other active ingredients in DIME development and reporting. This is also useful for subsequent DIME testing, fidelity assessment and dissemination. Chapter 3 and 4 moves

away from behaviour change techniques for now, but chapter 5 examines behaviour change techniques in relation to DIME development.

Chapter 3 ：*Experiences of attending group education to support insulin initiation in type 2 diabetes: a qualitative study*

3.1. Chapter scope

This chapter outlines study 2 of this thesis which has been peer-reviewed and accepted for publication in the Diabetes Therapy journal (Upsher et al., 2019). This chapter is an unformatted version of the publication with extra methodological detail. This chapter is a qualitative evaluation of an existing insulin start group currently run in south London. Views of people with type 2 diabetes who attended the insulin start group provide valuable insight into the development of the DIME intervention in terms of content and delivery.

3.2. Introduction

There are an estimated 422 million people with type 2 diabetes living with diabetes worldwide (WHO, 2016), costing world healthcare services over 827 billion US dollars (NCD, 2016; Seuring, Archangelidi, & Suhrcke, 2015). Type 2 diabetes is a progressive condition if not managed intensively with weight-loss strategies from diagnosis (Lean et al., 2018), and which are not achievable for many people. And even with optimal HbA1c and appropriate medication regimes, beta cell function deteriorates over time (Barag, 2011). Therefore, a large proportion of people with type 2 diabetes require insulin injections around 5-10 years from diagnosis, a treatment which is associated with improved HbA1c (Donnelly et al., 2007) and reduced risk of diabetes complications (Turner et al., 1999). With the growing population of type 2 diabetes, there has been a shift from initiating and managing insulin in secondary care to primary care (NHS, 2014). However, a recent United Kingdom survey found a shortage of diabetes specialists nurses/educators, fewer qualified nurses recruited into diabetes specialist roles, and an estimated 57% of diabetes specialist nurses due to retire within 10 years (DUK, 2016). Additionally, primary care nurses who are trained to support people with insulin education are also a limited resource. There's a similar picture in North America (Rizza et al., 2003). Therefore, there are fewer diabetes specialist nurses available with specialist skills to initiate insulin. A solution, requiring fewer specialists, is to provide insulin education in groups. Diabetes group education is cost-effective compared with individual support (Yki-Järvinen et al., 2007).

In the south London borough of Lambeth (United Kingdom), there is an existing 'insulin start group' for people with type 2 diabetes newly prescribed insulin therapy. The group is comprised of 2 sessions (2 hours each) 1 week apart to provide key educational and safety information around initiating and self-managing with insulin. The curriculum includes type 2 diabetes progression; safe insulin administration; insulin storage; dose titration; hypoglycaemia; driving with insulin; blood glucose readings review; sick day rules; travelling with insulin; and interpreting results of annual reviews. There are up to 6 people per group

and are facilitated by diabetes specialist nurses/educators. Referral to these insulin start groups is made by general practitioners in primary care. There is evidence that group education for people with type 2 diabetes can improve diabetes self-management and HbA1c (Chatterjee, Davies, Heller, et al., 2018; Deakin, Cade, Williams, & Greenwood, 2006; Loveman, Frampton, & Clegg, 2008; Scain, Friedman, & Gross, 2009; Trento et al., 2010), and is viewed favourably by healthcare professionals (Winkley et al., 2018). However, the evidence is for diabetes self-management education in general, less is known about type 2 diabetes insulin education groups.

People with type 2 diabetes have reported many negative beliefs around insulin therapy (Chatterjee, Davies, Heller, et al., 2018; Ellis et al., 2018; Ng et al., 2015), termed as psychological insulin resistance (Petrak et al., 2013; Peyrot et al., 2005; Polonsky et al., 2011) as outlined in the introduction of this thesis. However, there is currently no national or international guidance on how to address insulin concerns for people with type 2 diabetes (RCN, 2012) which could be incorporated into education groups to provide optimal support.

In summary, insulin education groups are useful to reduce the cost burden for health services; and maximise the expertise of diabetes specialist nurses as the number of people with type 2 diabetes continue to rise. Therefore, it is important to gauge the views of people with type 2 diabetes who have attended insulin education groups to identify views on the barriers to insulin self-management, and suggestions for additional support to maximise the potential of aiding insulin self-management in type 2 diabetes. The aim of this study was to examine the perspectives of people with type 2 diabetes who have attended nurse-led group-based insulin start group education.

3.3. Methods

This study employed a qualitative design using semi-structured one-to-one interviews of people with type 2 diabetes from south London. This qualitative research was reported according to the 'consolidated criteria for reporting Qualitative research checklist' (COREQ), appendix 3.1. Ethical approval was obtained by King's College Hospital (ref: 17/LO/0363). Information sheets and consent forms for study 2 can be found in appendix 3.2 and 3.3 respectively.

3.3.1. Recruitment and sample

English-speaking adults (≥18 years) with type 2 diabetes were invited to participate in the study if they had attended an insulin start group in south London and commenced insulin.

All participants received the same type of education facilitated by diabetes specialist nurses/educators at community venues in south London after receiving their first insulin prescription. People attending the insulin start groups started on once-daily basal insulin, with a starting dose of 10 units which they were taught how to titrate within the group. People with type 2 diabetes were purposively sampled by sex, age (</45, 46-59, 60+ years), and ethnicity (White, Black, South Asian/other).

3.3.2. Development of interview schedule

An initial interview topic guide was designed by 3 researchers (RU, KW, MA) based on current literature (*table 3.1)*. The interview schedule was assessed for face validity through discussion with healthcare professionals and piloting the interview on 2 people with type 2 diabetes who had attended an insulin start group, topics guides were then revised. For subsequent interviews, each researcher listened to audiotapes of interviews conducted by the other 2 researchers for fidelity purposes, allowing reflection and discussion of interview technique, and to identify any interviewer bias to be eliminated in subsequent interviews. Topic guides were revised as required to account for individual interviewing styles and for rigorous data collection.

Table 3.1- *Topic guide for study 2 interview schedule*

- Reasons for referral to the diabetes specialist team
- Need for insulin, barriers to uptake and adherence
    - Benefits of insulin
    - Disadvantages of insulin
    - Delay in insulin?
    - Concerns/worries before insulin initiation
- Views on insulin self-management support
    - Views on group insulin education
    - Positive views on insulin self-management support
    - Less positive/helpful aspects of on insulin self-management support
    - Readiness to initiate insulin
    - Follow-up support
    - Recommendations for future insulin education support

3.3.3. Data collection

Interviews were conducted by one of the 3 female researchers (RU, KW, MA) who had experience with conducting qualitative research and were based at King's College London, 2 researchers were also diabetes specialist nurses (MA, KW). Diabetes specialist nurses did not interview any person with diabetes for whom they had personally educated. Eligible participants were identified on Egton Medical Information Systems (medical record system) by diabetes specialist nurses on the research team who were then contacted via telephone and, if willing, arranged a date and time for the interview. Interviewees were given the choice of interview location to maximise recruitment: King's College London research

facility; or the participants' local general practice surgery. A family member or friend was invited to be present at the interview, if the interviewee desired.

Participants were informed the study was funded by the National Institute for Health Research and the specific purpose of the project was to determine views on the barriers to insulin self-management, views on diabetes education courses, and suggestions for additional support to aid insulin self-management in type 2 diabetes. Each participant was interviewed once. To ascertain adequate sample size, after every 3 interviews, the transcripts were assessed (by RU and KW) for information power based on study aim (views of insulin education received); sample specificity (people who attended an insulin start group and sample based on age, gender and ethnicity); quality of dialogue (assessed by the knowledge base of researchers as well as rapport between researcher and participants); and analysis strategy (outlined below) (Malterud, Siersma, & Guassora, 2016).

3.3.4. Data analysis

Interviews were transcribed and anonymised data from transcripts were managed in NVivo12 (qualitative computer software). Inductive thematic analysis identified themes within the data via 6 stages (Braun & Clarke, 2006): 1) familiarisation of data by reading of transcripts and listening to audiotapes, making field notes of initial impressions; 2) generation of initial codes (RU & MA; reviewed by KW); 3) Searching for themes by collating codes that depict the data; 4) Reviewing themes and making sure the themes apply accurately to all coded data; 5) Defining and naming each theme to describe which aspects of the data the theme represents; 6) Producing a final report. The data was examined to distinguish common perceptions across participants and differences by age and ethnicity.

3.4. Results

A total of 15 people with type 2 diabetes were recruited. The mean age was 61.40 (SD=10.58), the majority were female (53.3%), 60 years or over (53.3%), and Black African or Caribbean ethnicity (60%), (table 3.2, table 3.3). The mean diabetes duration was 11.33 years (SD=7.18). The mean HbA1c level was 73.53 mmol/mol (SD= 21.49). Diabetes treatment is reported in table 3.2. The most common insulin treatment was Humulin I (73.3%), and most common oral antidiabetic medication combination was Metformin, Gliclazide and Sitagliptin (33.3%). Three people were prescribed Glucagon-like peptide-1 treatment. No one dropped out of the study, 1 person declined to participate (lack of time), and there were 3 people who were eligible but did not respond to the research team. The mean duration of interviews was 28.10 minutes (SD=9.82).

The analysis generated three key themes: 1) creating a supportive environment; 2) facilitator skills; 3) effectiveness of group. There were further sub-themes within each theme (*figure 3.1)*.

1.Creating a supportive environment

An environment which best provided insulin self-management support consisted of three components including group members (peers), group facilitators, and supportive resources (printed materials).

a. Peer support

Many conveyed that being in a group was a positive supportive experience, for example, to hear different people's perspective, to share one's own experience, and being with other people with diabetes:

> *"…you can come in and then share your experience and also gain from other people's experience…" (13M)*

> *"You feel more comfortable, you are not the only one [with diabetes]…I was happy as well because I'm going to see other people as well." (08F)*

Another highlighted a sense of personal failure in relation to having to take insulin for their diabetes but feel comforted by a range of people in the group being in the same situation as themselves:

> *"… so thinking, "What have I done wrong?", but when you sit around, you see young ones, old ones, and everybody's been on it[insulin], it's kind of an inspiration."(12M)*

b. Providing reassurance

Reassurance was provided by the insulin group facilitator who would deliver important educational information such as frequency of injections:

> *"Well reassurance from them that it wasn't going to be a big task to take the injections every night and it was only one." (04M)*

The type of information was not the only important factor in providing reassurance but the way in which the information was communicated lead to feelings of empowerment:

> *"I was empowered, you know, the nurse explained a lot of things to us." (01F)*

c. Printed materials

For some, printed materials which were given to the group to take home were an informative resource to support the educational content and reinforce knowledge learnt:

> *"Yes, they are informative, you know, they have a lot of information that you need to know about diabetes and insulin, you know." (06M)*

> *"The leaflets were just a form of reinforcement, that's what they were." (15M)*

Others reported negatively on these resources which led to them being unread or thrown away, one explanation was this was due to being given too many leaflets:

> *"if you had a lot of papers, you know, some of it might go missing…but few I read honestly" (01F)*

> *"I probably binned them, but they were, they were useful at the time." (10F)*

Other interviewees suggested the printed materials were not suitable for all audiences such as those where English is not their first language:

> *"lots of information papers but they are too much to read, especially because English is not my language that's why maybe." (02F)*

2.Facilitator skills

It was important for facilitators to have the appropriate skills to manage concerns around insulin therapy within the groups. Managing group dynamics could be positively or negatively attributed to the skill of the facilitator.

a. Addressing negative insulin beliefs

One approach group facilitators used to address the fear of injections were practical demonstrations and practice of injecting which eliminated concerns for some:

> *"I had a go at doing the injection. And then, you know, I thought oh my God, this is fine." (01F)*

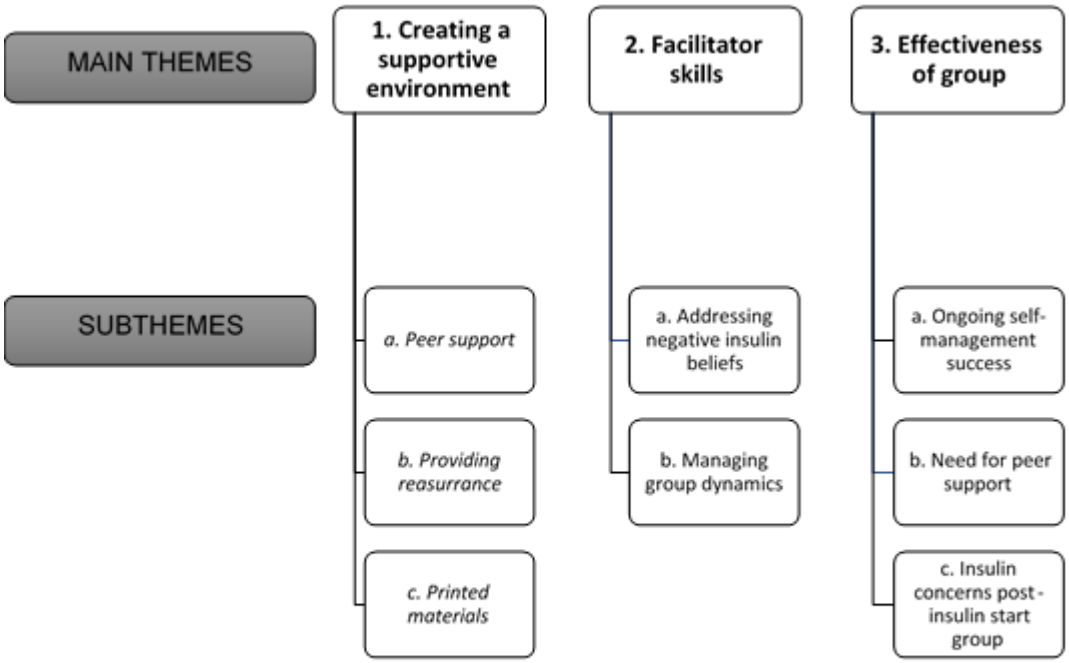

Figure 3.1- *Summary of themes and subthemes in study 2*

However, facilitators did not address fears for all, one interviewee described feelings of anxiety which prevented retention of information:

> *"… of course being human beings we sometimes shut down from things that we fear… So we don't necessarily take onboard as much as we could do were we not human beings that have fears and anxieties and personalities…" (03F)*

In addition, there was one account indicating the diabetes specialist nurse facilitator lacked skills to support fears around insulin:

> *"there was one lady who was really frightened…I noticed that the nurse wasn't persuading her or doing any other thing except just explaining what it[insulin] was…" (13M).*

Table 3.2- *Overall demographics of interviewees with type 2 diabetes in study 2*

Characteristics	N	%	Mean (SD)
Age			61.40 (10.58)
</45	2	13.3	
46-59	5	33.3	
60+	8	53.3	
Ethnicity			
Black African/Caribbean	9	60.0	
Caucasian	5	33.3	
Asian/other	1	6.7	
Gender			
Female	8	53.3	
Male	7	46.7	
Diabetes Duration			11.33 (7.18)
HbA1c			73.53 (21.49)
Insulin type			
Humulin I	11	73.3	
Novomix 30	2	13.3	
Lantus	1	6.7	
Abasaglar	1	6.7	
Oral antidiabetic medications			
Zero	2	13.3	
Gliclazide Only	2	13.3	
Metformin only	2	13.3	
Metformin and Gliclazide	2	13.3	
Metformin, Gliclazide, Sitagliptin	5	33.3	
Metformin, Gliclazide and Linagliptin	2	13.3	
Glucagon-like peptide-1			
Zero	12	80	
Dulaglutide	2	13.3	
Liraglutide	1	6.7	

b. Managing group dynamics

An interviewee described the importance of the diabetes specialist nurse facilitator allowing time for everyone's questions and managing different people within the group to check their understanding:

> *"Because they take a small number of people and the nurses … gives yourself time to talk to people individually and then, you know, some people… take time to digest information but then the nurse has got time to listen to those people and then explain further so that people understand the session." (01F)*

Table 3.3-*Demographics of each interviewees with type 2 diabetes in study 2*

Participant number	Age group	Sex	Ethnic group
1	46-59	Female	Black African/Caribbean
2	60+	Female	Asian/other
3	60+	Female	White
4	60+	Male	White
5	46-59	Female	Black African/Caribbean
6	60+	Male	Black African/Caribbean
7	</45	Male	Black African/Caribbean
8	46-59	Female	White
9	60+	Female	White
10	60+	Female	White
11	60+	Female	Black African/Caribbean
12	46-59	Male	Black African/Caribbean
13	60+	Male	Black African/Caribbean
14	46-59	Male	Black African/Caribbean
15	</45	Male	Black African/Caribbean

There were however reports of frustration around listening to other group members experiences indicating group dynamics were not well managed in some cases:

> *"…listening to other people's experience, plenty of time was given so people could go on and on and on, that may be something to manage, yeah, because people can go into their lifetime stories and many of them moved away from the point being discussed." (13M)*

In related accounts, a preference for one-to-one education was expressed so questions could be answered unlike their experience within a group:

> *"You know, we're in a group, you can't keep on asking questions when other people have their hands up…if it's like one-to-one thing you've been apportioned a time, like fifty minutes I'm going to be with you, ask all the question..." (12M)*

There was an indication that people in the group were at different 'levels' including insulin experience (i.e. previously on injection therapy) and age, these factors were not controlled within the group setting:

> *"I'm more experienced than they are… I've been injecting myself* [previously]*, so it, it was a bit pedestrian for, really it was a bit pedestrian…it wasn't the same for me as it was for these people trying to learn how to inject themselves." (10F)*

> *"…the kind of only daunting thing for me was that when you're seeing a lot of people much, much older around you [in the group]…" (07M)*

3.Effectiveness of group

By gauging knowledge and beliefs of people who had attended insulin group education, inferences could be made about the effectiveness of the group. Subthemes which were indicators of effectiveness of the insulin group include: ongoing management success, need for more peer support, and insulin concerns post-group.

a. Ongoing self-management success

Success of insulin self-management post-insulin group was highlighted by improvement in blood glucose levels:

> *"…my sugar levels are down. I'm a happy person." (01F)*

However, not all diabetes self-management feedback post-insulin group was positive. For example, groups did not appear to take into consideration cultural differences in diet and lifestyle, with one report of need for education around Afro-Caribbean diets and diabetes:

> *"… with the greatest respect there is the marked difference between a Western diet and Afro-Caribbean and even an Asian diet, there's a marked difference. So...with the best of intentions making a suggestion to somebody from another culture without understanding their own diet, the advice might sound alien…" (15M)*

Other self-management techniques which required more attention in insulin groups included injection technique, and describing the different types of insulin:

> *"I find the actual injection thing, I find it very hard to press it, because you're holding your... you know, and then you have to put it in, I find that very hard…" (09F)*

> *"I thought they should have explained to us why some people, they call it active, instant reacting insulin, why are some people on that and some people on the other one?" (12M)*

There was also lack of knowledge around knowing how to react to pseudo hypoglycaemia. This is an event of hypoglycaemia symptoms that can occur when blood glucose levels are >3.9 mmol/L(70mg/dl) (i.e. not hypoglycaemic levels) resulting from previous exposure to long term hyperglycaemia:

"I woke up this morning feeling a bit, I don't know, I haven't felt like this for a long time, I feel dizzy. In fact, I took my, when I was not feeling well, I took my blood to test it. It wasn't even on hypo level, so I don't know why I was feeling like that..." (11F)

b. Need for more peer support

Need for further peer support beyond the insulin education groups was indicated by wanting more social activities and meeting up with group member living close by:

"But then they can always encourage that little group that's local to each other. I don't know whether you realise it but like there's six of you in this room at the moment that are all within a mile of each other." (03F)

Also, some expressed a desire for follow-up group or 'booster' sessions to refresh content learnt in groups:

"how to put that into refresh my mind for that to come up, plus I used to forget something, very soon I will forget everything, yeah." (14M)

However, others were content with the original 2 sessions:

"The two groups were just right." (13M)

Not only face-to-face support was mentioned, but one participant shared their positive experience of peer support via a web support group to ask questions about diabetes and insulin:

"I'm able to contact other people and if I have questions I'm able to post it and have somebody who's had that experience so it's a continuous thing." (13M)

c. Insulin concerns post-group

There were some positive accounts of insulin therapy such as confidence in insulin efficacy and taking insulin, and improved well-being:

"I felt confident to start it and since then I've been doing it." (06M)

"It's made me, you know, feel myself again." (01F)

However, interviewees did recount a range concerns which remained post-insulin group such as injecting for life, hypoglycaemia, where to inject, and weight gain. This suggests the insulin groups were not effective in eliminating all concerns around insulin therapy:

"Just think about injecting myself for the rest of my life, I think that's one of the biggest disadvantage for me you know" (07M)

"The hypo quite a lot…I feel quite dizzy." (11F)

"I'm having a problem with the injection, you know, that is locating areas in my tummy where to inject" (06M)

"I noticed that I put on weight with insulin." (12M)

Another concern from one interviewee was travelling with insulin, which now prevented him from seeing friends as he did not want to take insulin with him:

"Even I go and stay with a friend of mine down in Crawley and since I've been on insulin I haven't been down to see him because I don't want to be taking medication down with me." (04M)

3.4.1. Common perceptions across participants and difference by ethnicity and age

Irrespective of ethnicity or age, there were common perceptions across participant groups, for example, positive interactions meeting others with type 2 diabetes, sense of reassurance from nurse facilitator, mixed feelings towards printed materials, desire for psychological support, mixed sense of how facilitator managed group dynamics, improvement in blood glucose post insulin initiation yet challenges with injection technique, desire for more peer support or content with existing level of education, and post-group concerns (where to inject, insulin a lifelong treatment, travelling with insulin, hypoglycaemia). Common perceptions and differences by ethnicity and age are summarised in table 3.4. Mostly, there were no distinguishable differences between ethnicity or age groups. The 60+ age group seemed to express the need for psychological support more than the other age groups, this age group also reported desire for more social activities within the insulin education groups and seeking further peer support online. Black African/Caribbean participants were the only ethnic group to highlight the lack of consideration for cultural differences in diet and lifestyle, in addition to having concerns about weight gain on insulin treatment.

Table 3.4- *Commonalities and differences in ethnicity and groups for people with type 2 diabetes who attended an insulin start group*

Theme	Common perceptions across groups	Differences by ethnicity	Differences by age
1a. Peer Support	Feelings of encouragement from meeting and attending a group with other people with type 2 diabetes starting insulin.	No distinguishable differences.	No distinguishable differences.
1b. Providing reassurance	The nurse facilitator provided reassurance and empowerment, who explained things well and was friendly.	The Asian/other participant did not provide comment regarding reassurance from the nurse facilitator. There were no distinguishable differences between Black African/Caribbean and Caucasian ethnicity.	No distinguishable differences.
1c. Printed materials	Too many printed materials provided. For some printed materials provided useful information and were kept so they could refer to them in future. Others did not keep printed materials.	Black African/Caribbean and Asian/other (but not Caucasian) participants discussed language barriers in reading printed materials and that too many printed materials were provided. Some Black African/Caribbean and Caucasian (but not Asian/other) participants felt printed materials contained useful information and kept them for future reference, others discarded them.	Both 46-59 and 60+ age groups (</45 age group did not comment) remarked on language barriers, too many printed materials provided, or printed materials were kept for future reference.
2a. Addressing negative insulin beliefs	Some concerns around insulin were addressed, desire for psychological support.	Black African/Caribbean participants found practical demonstration on insulin injections useful (Caucasian and Asian/other participants did not comment on this).	Both 46-59 and 60+ age groups found practical demonstration on insulin injections useful and some felt concerns around insulin were addressed. The 60+ age ground desired psychological support.
2b. Managing group dynamics	Nurse facilitator allowing time for everyone's questions, frustration of listening to other group members experiences, preference for one-to-one	No distinguishable differences.	No distinguishable differences.

	education, people with different 'levels' in group (e.g. knowledge or age)		
3a. Ongoing self-management success	Improvements in blood glucose post insulin group, some issues with injection technique and challenges with diet.	Some Caucasian and Asian/other participants found it easy to inject. Other Caucasian and some Black African/Caribbean participants desired more education on injection technique post-group. Black African/Caribbean participants highlighted the lack of consideration for cultural differences in diet and lifestyle, and confusion around pseudo-hypoglycaemia.	</45 age group highlighted the lack of consideration for cultural differences in diet and lifestyle. 60+ age group had confusion around pseudo-hypoglycaemia.
3b. Need for peer support	Some desired more follow-up sessions, others were content with existing level of insulin education.	Caucasian participants wanted more social activities. Black African/Caribbean participants sought more peer support via online forums.	60+ age group showed interest in more social activities and sought more peer support via online forums.
3c. Insulin concerns post-insulin start group	Concerns around where to inject, insulin being a lifelong treatment, travelling with insulin and hypoglycaemia.	Black African/Caribbean participants had concerns over insulin and weight gain.	The 46-59 ae group had concerns over insulin and weight gain.

3.5. Discussion

The aim of this qualitative interview study was to identify perceptions of group insulin education for people with type 2 diabetes. Interviews of people with type 2 diabetes who had attended group insulin education in south London revealed three main themes: creating a supportive environment, facilitator skills, and effectiveness of group.

3.5.1. Creating a supportive environment

Social support including peer support is important for improving outcomes in type 2 diabetes (Stopford et al., 2013; Strom & Egede, 2012). In study 2 of this thesis, peer support in insulin group education was found to be associated with positive experiences as well as reducing personal failure related to starting insulin by being around other people in the same situation.

Previous research indicates acceptance of insulin therapy is associated with healthcare professional support (Hassan et al., 2013). Diabetes nurses/educators providing reassurance was found to be beneficial in the analysis of thesis study 2. Reassurance was also achieved by providing important educational information as well as the way in which information was communicated to empower the group.

Printed materials were given to group members to support learning. These generated mixed reviews, some finding them informative and others criticising the volume of paperwork. These materials were also difficult for those whose first language was not English. Further consideration is required to make resources equitable for all.

3.5.2. Facilitator skills

Previous research has indicated starting insulin can decrease negative insulin beliefs such as fears of hypoglycaemia (Hajós et al., 2011). However, it is unknown whether this is related to receiving certain types of insulin education or the skill of the diabetes nurse/educator. Study 2 of this thesis found fears of injecting were addressed in group insulin education through practical demonstrations and practicing injecting in the group. This is supported by the wider literature where there is evidence that receipt of practical advice such as, insulin injection demonstrations, help people with type 2 diabetes avoid delays in initiating insulin (Polonsky et al., 2019).

However, not all interviewees in study 2 of this thesis study were satisfied and communicated the facilitator lacked skills to support or address their fears and anxiety around insulin therapy. In addition, in some circumstances facilitators did not manage group dynamics well and some participants expressed concerns as some of the diabetes nurses did not answer everyone's questions, and were not effective at managing people at different life stages for example level of insulin knowledge and experience or age group. Whilst some diabetes specialist nurses delivering insulin start groups in south London might have had some group education training for other diabetes education groups, for example, DESMOND (Diabetes Education and Self-Management for Ongoing and Newly Diagnosed), they are often expected to run insulin start groups without formal training. There is no current accredited group insulin education training in the UK which may account for inconsistences in facilitator skill. Meta-analyses have demonstrated that psychological interventions using cognitive behavioural therapy and counselling can help support people with type 2 diabetes to self-manage and improve HbA1c (Alam et al., 2009; Ismail et al., 2004; Winkley et al., 2019). Whilst, some of the included studies were delivered to groups of people, they were not specifically related to insulin initiation. However, facilitators

trained in these psychological skills might be better equipped to addressed insulin concerns in a group setting.

3.5.3. Effectiveness of group

Previous research related to group type 2 diabetes education has demonstrated improvements in HbA1c (Chatterjee, Davies, Heller, et al., 2018; Deakin et al., 2006; Loveman et al., 2008; Scain et al., 2009; Trento et al., 2010). Findings of study 2 of this thesis provide further support for group type 2 diabetes education with interviewees providing accounts of improved blood glucose readings post insulin education group. There were also negative reports including lack of consideration for cultural differences in relation to dietary content. It is important to consider these differences as culturally appropriate education for people with type 2 diabetes is associated with improvement in HbA1c and knowledge compared with untailored group education (Hawthorne, Robles, Cannings-John, & Edwards, 2010).

The insulin start group education delivered to participants in this study are not equivalent to structured education (with a manualised evidence-based curriculum), hence this may account for descriptions of missing elements of insulin education such as injection technique, types of insulin and hypoglycaemia awareness in some groups. An insulin education group which is defined as structured education according to UK guidelines (NICE, 2011; SIGN, 2017), could eliminate inconsistency in curriculum between groups.

The need for more peer support which was indicated by desire for social activities, group booster sessions and web support might suggest that the insulin group was not entirely successful in terms of providing support necessary to independently self-manage. Nevertheless, additional peer support may help support self-management in the longer term where group diabetes education has previously found to be unsuccessful (Khunti, Gray, et al., 2012b; Rankin, Cooke, Elliott, Heller, & Lawton, 2012).

3.5.4. Strengths and limitations of current research

A strength of the findings of this thesis study is the transferability of the results. Ultimately determining the transferability of the results is down to the reader who decides whether they can be applied to another sociocultural setting (Kuper, Lingard, & Levinson, 2008) and this can be aided by applying study results to existing theoretical health models. This study can be applied to the COM-B ('capability', 'opportunity', 'motivation' and 'behaviour') health behaviour model (Michie et al., 2011). For example, ‘Ongoing self-management success’ (theme 3.1) relates to the capability of self-managing with insulin in terms of

knowledge and skill. The theme 'Insulin concerns post-group' (theme 3.3) relates to the motivation to use insulin therapy (e.g. confidence to inject and plans to do so). Finally, 'Need for more peer support' (theme 3.2) relates to the opportunity to self-manage with insulin in terms of physical opportunity (e.g. travelling with insulin) or having social support. Furthermore, this supports using the COM-B model to re-design future insulin education interventions.

Although, the sample was limited to south London, this area is diverse in terms of ethnicity and socio-economic status and the sampling strategy took this into consideration. Therefore, what is learnt from this population is likely to be transferable to other areas of the UK and western Europe. Recruitment of majority Black African or Caribbean ethnic group was considered an advantage due to the large population of people from non-white European ethnicity in south London. Even though the minority of the sample was of south Asian ethnicity, difficulty in recruiting this demographic was anticipated owing to previous research of people with type 2 diabetes from south London (Winkley et al., 2015; Winkley et al., 2018). This group has a low prevalence compared with other ethnic groups therefore there was a smaller pool of people from this ethnic group to sample who had attended an insulin start group. Another limitation is current medications were not assessed so are unable to distinguish whether perceptions of group insulin education vary for those on differing treatments. Although, audiotapes were accurately transcribed and there was consistency between the data presented and findings, a potential limitation is transcripts were not returned to participants for comment or correction, and participants did not provide feedback on findings. In future research these additional measures could be taken to determine whether participants provide further insight post-interview.

3.5.5. Conclusions

This study highlights the importance of peer support and facilitator skill in creating a positive supportive environment in group insulin education. However, diabetes specialist nurses delivering group insulin education may need to develop psychological skills to enhance patient-communication, better manage group dynamics, and to address concerns around insulin therapy. In addition, insulin group content and supporting printed materials need to be further developed to be equitable to all regarding language and cultural differences. Follow-up peer support could be useful in optimising ongoing insulin self-management. This study provides a foundation for developing structured insulin education groups, and subsequently informing standardised treatment guidance around insulin education.

3.6. Chapter summary

The findings of this study 2 indicate that people with type 2 diabetes starting insulin often positively benefit from being educated in a group. Healthcare professional reassurance as well as practical injection demonstrations are important aspect to emphasise in DIME intervention to empower the group. Psychologically trained healthcare professionals who can manage group dynamics and address concerns could also be a beneficial aspect to DIME over current insulin start groups. This study provides further rationale for development of DIME and creating a new psychological education group for people with type 2 diabetes starting insulin. The next chapter examines the association between psychological factors and insulin related outcomes.

Chapter 4 : *Prospective study of the association between psychological factors at type 2 diabetes diagnosis and insulin initiation*: South London diabetes (SOUL-D) cohort

4.1. Chapter scope

This chapter describes study 3 of this thesis. For people with type 2 diabetes, delay in initiating insulin in the UK is a significant problem. While the reasons are complex and multifactorial, psychological factors are understudied. This chapter examines the prospective relationship between psychological factors (depressive symptoms, diabetes distress and negative insulin beliefs) measured at type 2 diabetes diagnosis and a) time to insulin-requiring status, and b) time to insulin initiation.

4.2. Introduction

4.2.1. Psychological factors and insulin-related outcomes

There are two key insulin-related outcomes. The first is at the point after diagnosis a person with type 2 diabetes medically needs insulin treatment termed in this thesis as 'insulin-requiring status.' This thesis chapter defines 'insulin-requiring status' according to NICE guidelines i.e. NICE recommend insulin initiation when dual OAD therapy does not result in optimal HbA1c (<58mmol/mol) (NICE, 2017). The second insulin-related outcome is the point after diagnosis a person with type 2 diabetes is first prescribed insulin termed in this thesis as 'insulin initiation'. This distinction is important as there can be a delay from requiring to receiving insulin therapy.

4.2.1.1 Depression and insulin-related outcomes

For people with type 2 diabetes, depressive symptoms are twice as common than the general population (Ali, Stone, Peters, Davies, & Khunti, 2006; Anderson, Freedland, Clouse, & Lustman, 2001; Krishna, 2018; Moulton, Hopkins, Ismail, & Stahl, 2018). Not only is depression associated with increased risk of type 2 diabetes (Kan et al., 2013; Knol et al., 2006; Mezuk et al., 2013; Nouwen et al., 2010; Rotella & Mannucci, 2013; Yu, Zhang, Lu, & Fang, 2015), but diabetes is a risk factor for depression (Chireh, Li, & D'Arcy, 2019).

In type 2 diabetes, depression is associated with poor diabetes self-care (Nanayakkara et al., 2018) including poor diet (Gonzalez, Safren, et al., 2008; Park, Hong, Lee, Ha, & Sung, 2004), less physical activity (Gonzalez, Safren, et al., 2008), poor treatment adherence (DiMatteo, Lepper, & Croghan, 2000; Gonzalez, Peyrot, et al., 2008), social isolation (Feng & Astell-Burt, 2017), poor attendance to diabetes education programmes (Park et al., 2004; Schwennesen, Henriksen, & Willaing, 2016; Winkley et al., 2015) and more hypoglycaemia (Biggers et al., 2019). Depression and reduced diabetes self-care are associated with increased glycaemic levels (Katon et al., 2010; Lustman et al., 2000; Richardson, Egede, Mueller, Echols, & Gebregziabher, 2008), long-term complications (Lin et al., 2010; Pouwer, Nefs, & Nouwen, 2013) and mortality (Ismail, Winkley, Stahl, Chalder, & Edmonds, 2007; Lin et al., 2009). In

relation to insulin therapy, depressive symptoms are also associated with negative insulin beliefs (Gherman & Alionescu, 2015) and spending more time to adjust to insulin therapy e.g. more time training to inject (Dzida et al., 2015). To date, there are no studies which examine the prospective relationship between depressive symptoms and time to insulin-requiring status. Previous evidence finds depressive symptoms do not appear to be associated with time to insulin initiation (Iversen et al., 2015; Nefs, Pop, Denollet, & Pouwer, 2013). However, these studies recruited insulin naïve people with established type 2 diabetes but from time of type 2 diabetes diagnosis which is a potential residual confounder.

4.2.1.2. Diabetes distress and insulin-related outcomes

Diabetes distress in type 2 diabetes is an umbrella term (Robinson et al., 2018) for a number of potentially overlapping psychological constructs including:

1) emotional burden

2) diabetes self-management

3) social relationships

4) healthcare professional relationship

Even though the prevalence of diabetes distress is higher in people with depressive symptoms and type 2 diabetes (Fisher et al., 2009; Perrin, Davies, Robertson, Snoek, & Khunti, 2017), factor analysis have found that depressive symptoms and diabetes distress are two separate constructs (Schmitt et al., 2014). To support this, some researchers have observed that diabetes distress, but not depression, is associated with higher glycaemic levels (Fisher et al., 2010; Tsujii, Hayashino, Ishii, Distress, & Group, 2012) and other studies find people with type 2 diabetes might have high diabetes distress but not depressive symptoms (Snoek et al., 2012). This suggests the importance of examining diabetes distress and depressive symptoms as separate factors in examining the relationship to insulin-related outcomes.

Diabetes distress is associated with poor treatment adherence (Gonzalez, Kane, Binko, Shapira, & Hoogendoorn, 2016), worsening glycaemic levels (Aikens, 2012; Gonzalez, Shreck, Psaros, & Safren, 2015; Hayashino et al., 2012; Tsujii et al., 2012; Winchester, Williams, Wolfman, & Egede, 2016), and a higher risk of mortality (Dalsgaard et al., 2014). Makine et al demonstrated that for people with type 2 diabetes, higher scores for depressive symptoms and diabetes distress was associated with higher negative insulin beliefs (Makine et al., 2009). In addition, there is evidence that diabetes distress mediates the relationship between depression and glycaemic levels (Van Bastelaar et al., 2010). These studies were cross-sectional and did not

examine the direction of association i.e. whether depression comes first and leads to distress which leads to reduced self-care and therefore worsens glycaemic levels. Or whether reduced self-care comes first and leads to diabetes distress. There are no studies which examine whether diabetes distress is associated with earlier onset of becoming insulin requiring or earlier onset of insulin initiation.

4.2.1.3. Negative insulin beliefs and insulin-related outcomes

Insulin initiation necessitates a 'willingness' to use insulin as well as minimal negative insulin appraisals (Holmes-Truscott et al., 2017), suggesting negative insulin beliefs could delay insulin initiation. Negative insulin beliefs pre-insulin initiation were associated with a delay in insulin initiation, specifically four factors on the modified Insulin Treatment Appraisal Scale (mITAS): 'concerns about injections', 'failed diabetes management', 'increased disease severity', and 'concerns about side effects' (Hessler et al., 2018). These studies were cross-sectional and the longitudinal association between negative insulin beliefs and earlier onset of becoming insulin-requiring or initiating insulin has not been studied.

4.2.2. Other factors associated with insulin initiation

Socio-demographic factors that are associated with delayed insulin initiation include older age (Hassali et al., 2014), higher body mass index (Lakkis, Maalouf, Mahmassani, & Hamadeh, 2013b; Nefs et al., 2013), ethnic minorities e.g. black African and south Asian (Bellary et al., 2008; Millett et al., 2007), higher glycaemic levels (Holmes-Truscott et al., 2017) and higher cardiovascular risk (Khan et al., 2008).

Another socio-environmental factor is the law. People with diabetes in the UK must inform the driving licence authority when they initiate insulin therapy, and licence renewal is required every 3 years (GOV.UK, 2019). Fear of hypoglycaemia can be associated with driving occupation (Barendse et al., 2012). In the UK, people with type 2 diabetes who drive for their occupation and require a group 2 licence (for example, bus or lorry drivers) are requested to submit 3 months of blood glucose meter readings after starting insulin. Hypoglycaemia can prevent them from obtaining a licence (DUK, 2019). The threat of not being able to work could be enough to deter someone from wanting to initiate insulin therapy, and hence this barrier should be taken into consideration when studying time to insulin initiation.

4.2.3. Factors associated with psychological factors

There are socio-demographic and clinical factors associated with depressive symptoms, diabetes distress and negative insulin beliefs. For example, in people with type 2 diabetes, there is an association between the presence of depressive symptoms and a number of factors including higher glycaemic levels (Katon et al., 2010), presence of macrovascular complications

(Ismail et al., 2017), and female sex (Ali et al., 2006; Alonso-Morán, Satylganova, Orueta, & Nuño-Solinis, 2014). Factors associated with type 2 diabetes distress are younger age, being female, ethnic minority, higher body mass index, higher glycaemic levels, and more diabetes complications (Peyrot, Rubin, & Polonsky, 2008; Pintaudi et al., 2015; Stoop et al., 2014; Wardian & Sun, 2014). Negative insulin beliefs are associated with ethnic minorities and female sex (Nam, Chesla, Stotts, Kroon, & Janson, 2010) in people with type 2 diabetes. It is important to examine these socio-demographic factors as potential confounders in the relationship between psychological factors and insulin-related outcomes.

4.2.4. The south London diabetes cohort

In the original **SOU**th **L**ondon **D**iabetes (SOUL-D) study (baseline), newly diagnosed (within 6 months) people with type 2 diabetes were recruited between 2008 and 2012 from primary care in the boroughs of Lambeth, Southwark, Lewisham and Bromley in south London (Winkley et al., 2013). One hundred and thirty-eight general practices were invited to participate, 96 consented to participate and 1735 people with type 2 diabetes were consented and seen. The original SOUL-D cohort has been followed-up at 1-years and 2-years. Study 3 of this thesis follows up the original SOUL-D cohort 8-years later, i.e. the 8-year follow-up SOUL-D study. In the primary analysis, depressive symptoms at diagnosis of type 2 diabetes were not associated with worsening HbA1c over 2-year follow-up. Despite this, depressive symptoms at baseline were associated with a greater incidence rate of macrovascular complications at 2-year SOUL-D follow-up (Ismail et al., 2017). The 8-year follow-up SOUL-D study aims to examine depressive symptoms at baseline as well as other psychological factors (diabetes distress and negative insulin beliefs), and time to insulin-related outcomes.

4.2.5. Current study aims and hypotheses

The aim of study 3 of this thesis, the 8-year follow-up SOUL-D study, was **t**o examine the association between i) depressive symptoms, ii) diabetes distress iii) negative insulin beliefs on a) time to insulin-requiring status and b) time to insulin initiation.

The 8-year follow-up SOUL-D study tested the hypotheses that:

1) Higher depressive symptoms in newly diagnosed people with type 2 diabetes were associated with a shorter time to a) insulin-requiring status, and b) insulin initiation.

2) Higher diabetes distress in newly diagnosed people with type 2 diabetes was associated with a shorter time to a) insulin-requiring status, and b) insulin initiation.

3) Lower negative insulin beliefs in newly diagnosed people with type 2 diabetes were associated with a shorter time to a) insulin-requiring status, and b) insulin initiation.

4.3. Methods

4.3.1. Design and setting

This was an 8-year follow up of people with type 2 diabetes from the original SOUL-D prospective cohort study who consented to medical record follow-up.

4.3.2. Ethical considerations

Ethics for the original SOUL-D study was approved by King's College Hospital Research Ethics Committee (reference 08/H0808/1) and by Lambeth, Southwark, and Lewisham Primary Care Trusts (reference RDLSLB 410). In addition, ethics was requested for the follow-up study by King's College Hospital (reference 17/EE/0272) and Dulwich research ethics committee (reference 08/H0808/1). The medical records of participants in the original SOUL-D study who consented to 20 years follow-up were screened for the 8-year follow-up SOUL-D study. It was not necessary to re-consent participants to screen medical records for follow-up, however, participants were sent a letter to inform them that their data was to be used in line with the health research authority standardised General Data Protection Regulation outline (HRA, 2018) (see appendix 4.1).

All personal data were kept confidential in line with NHS Code of Confidentiality. Once a participant in the original SOUL-D study provided informed consent, they were assigned a participant ID (identification) number for the study. The ID number was recorded on all study documents in the original and 8-year follow-up SOUL-D studies, including original study questionnaires and 8-year follow-up medical records data collection schedule. The participant's name was not recorded on any study documents other than the informed consent form and Participant ID log.

Contact details (email, telephone numbers, and/or addresses) of participants were kept in a file, in a locked filing cabinet in a locked office at a King's College London campus. The original SOUL-D study questionnaire assessments and lab data were also kept in a separate file in a locked room at a King's College London campus. Follow-up medical records data collection was entered electronically only and was stored on a University password-protected computer in a locked office at the University. Only the research team had access to computers which contained data for this research, in addition to locked filing cabinets/rooms.

4.3.3. Participants and inclusion/exclusion criteria

People with type 2 diabetes were recruited in the original SOUL-D study within 6 months of type 2 diabetes diagnosis. Type 2 diabetes diagnosis was made in accordance with the World Health Organization criteria (WHO, 1999) and validated by a review of participant medical records. World Health Organisation criteria recommend the following combination and

repetition of tests to diagnose type 2 diabetes: fasting plasma glucose (> 7.0 mmol/L); random plasma glucose (≥11.1 mmol/L); 2-hour post 75g oral glucose tolerance test (≥11.1 mmol/L); HbA1c tests (≥ 48 mmol/mol).

The inclusion criteria for the original SOUL-D study were adults with type 2 diabetes (18-75 years). The exclusion criteria were: >6 months type 2 diabetes duration; other diabetes types (type 1 diabetes or gestational diabetes); not fluent in English; residing outside of south London; current severe mental health condition e.g. dementia, personality disorder, bipolar disorder, substance dependence; advanced or terminal condition; and advanced diabetes complications (registered blind, dialysis, above knee amputation).

4.3.4. Measures/materials

Table 4.1 summarises the exposure and outcome factors and how they were measured. The original SOUL-D study factors are referred to as baseline factors. Medical records for the 8-year follow-up SOUL-D data collection were accessed via Egton Medical Information Systems (EMIS) web (EMIS, 2016) at the participants' general practice surgeries and entered into a standardised Microsoft Excel data collection schedule.

4.3.4.1. 8-year follow-up SOUL-D descriptive data

Follow-up time. The time from the original SOUL-D data collection to the 8-year follow-up SOUL-D was calculated in months.

Active status. EMIS indicated whether the participant was active, deceased or inactive. 'Active' refers to the participant currently accessing healthcare at the surgery. 'Inactive' refers to the participant previously accessing healthcare at the surgery but have since moved to another surgery. A blue band at the top of the EMIS screen indicated the participant was active, a red band for deceased, and a grey band for inactive. A deceased variable was coded as yes (deceased), no (active and not deceased) or inactive (inactive). Reason for death was also recorded via the 'problems' or 'documents' tab in EMIS.

HbA1c. A history of HbA1c measurements was recorded via the 'investigations' tab in EMIS, every HbA1c measurement was recorded since type 2 diabetes diagnosis. HbA1c was recorded in mmol/mol, if reported in % HbA1c in EMIS it was transformed into mmol/mol via an online HbA1c converter. Date of HbA1c measurement was also extracted.

OADs. A history of types of OADs were recorded via the past and current 'medication' tab in EMIS. Start and stop date was recorded for previous OADs and start date for current OADs.

Other injectables. Injectables, not including insulin treatment, were recorded via the past and current 'medications' tab in EMIS. Types of other injectables included: exenatide, liraglutide, dulaglutide, and insulin degludec plus liraglutide. Start and stop date was recorded for previous other injectables and start date for current other injectables.

Insulin treatment. Insulin treatment was identified via the past and current 'medication' tab in EMIS. Type of insulin was recorded including fast-acting insulin (insulin lispro, insulin aspart, insulin glulisine, soluble insulin); long-acting insulin (insulin glargine, insulin determir, Toujeo, humulin M3, insulatard); intermediate-acting insulin (NPH); pre-mixed insulin (Humalog Mix 50, Novo mix 30).

4.3.4.2. Exposure baseline psychological factors

Depressive symptoms: Patient health questionnaire (PHQ-9). This 9-item, self-report questionnaire was used to assess depressive symptoms over the last 2 weeks (Kroenke, Spitzer, & Williams, 2001). Responses were based on a 4-point Likert scale ranging from 'not at all (score=0)' to 'nearly every day (score=3)'. For example, 'how often have you been (how much have you been) bothered by…little interest for pleasure in doing things?' Overall questionnaire scores ranged from 0-27, with higher scores indicating more depressive symptoms. This factor can be used as continuous or categorical. For PHQ-9 categorical, a ≥10 score was the cut-off indicating the caseness for probably depressive disorder. The tool has been validated in the SOUL-D sample using a two-stage survey design comparing the PHQ-9 against a gold standard diagnostic interview (Twist et al., 2013). This tool is often used in primary care as it is free and easy to administer with little training. In addition, the PHQ-9 has good internal consistency (Cronbach's α=0.85), meaning the questionnaire often detects depression when depression is present (Kroenke et al., 2001).

Diabetes distress: Problem areas in diabetes (PAID) questionnaire. This 20-item self-report questionnaire assesses current diabetes distress and emotions experienced when coping with diabetes (Polonsky et al., 1995). Items are measured on a 5-point Likert scale from 'not a problem (score=0)' to 'serious problem (score=4).' For example, 'Not having clear and concrete goals for your diabetes care?' Responses for all items are summed and multiplied by 1.25 to derive generate an overall score between 0-100. Scores can be continuous or categorical. PAID was used as a categorical factor for the follow-up study where ≥40 scores represented a high diabetes distress/emotional. This scale has high internal consistency (Cronbach's α=0.95) (Welch, Jacobson, & Polonsky, 1997). The PAID scale has concurrent validity as it was highly correlated with previously established scales measuring similar constructs including four coping subscales (diabetes integration coping, avoidance coping, passive resignation coping,

tackling spirit coping), Health Belief Model scale and the Diabetes Social Support Measure (Welch et al., 1997). In addition discriminant validity was found by detecting differences in PAID scores between type 1 diabetes and type 2 diabetes groups (Welch et al., 1997).

Negative insulin beliefs: Barriers to insulin treatment (BIT) questionnaire. This 14-item self-report questionnaire assesses beliefs around insulin injection therapy in response to various statements (Petrak et al., 2007). People with type 2 diabetes on any or no treatment can answer this questionnaire as it assesses beliefs towards insulin regardless of current diabetes treatment. BIT items comprise of a 10-point scale ranging from 'totally disagree (score=1)' to 'totally agree (score=10),' with a score of 5-6 indicating an unsure response to the statement. An example statement is: 'I am afraid of the pain when injecting insulin'. This questionnaire comprises of 5 subscales: fears of injections & self-testing (subscale 1, items 1-3); expectations regarding positive insulin-related outcomes (subscale 2, items 4-6); expected hardship from insulin therapy (subscale 3, items 7-9); stigmatisation by insulin injections (subscale 4, items 10-12); fear of hypoglycaemia (subscale 5, items 13-14). Subscale 2 was reversed scored as higher scores on these items indicate low negative insulin beliefs, whereas higher scores on the other subscales indicate high negative insulin beliefs. To calculate the overall BIT scores, scores for all items were summed and mean scores ≥5.57 indicate high negative insulin beliefs (Boughdady, Winkley, Ismail, & Amiel, 2014). This tool is reliable, finding high internal consistency between subscales (Cronbach's α= 0.78) and has predictive validity in two cross-sectional studies of people with type 2 diabetes who have never been on insulin treatment (*d*=0.76) (Petrak et al., 2007).

4.3.4.3. Insulin-related outcomes: 8-year follow-up SOUL-D data collection

Insulin-requiring status. Participants were identified as requiring insulin according to NICE guidelines which stated: despite being on 2 OADs, the person with type 2 diabetes has suboptimal HbA1c (≥58 mmols/mol) (NICE, 2009). The date at which a participant started a second OAD was compared to HbA1c lab test data. One month after a second (or more) OAD was prescribed, and if the HbA1c was ≥58mmol/mol, this was coded as insulin-requiring and the date at which this first occurred was recorded. One-month (or more depending on available data) was selected as the duration post prescription of the second OAD because it allowed time for this medication to take effect, as opposed to coding as becoming insulin-requiring in the month the person started the second OAD.

Insulin initiation. Insulin initiation was defined as the date of first insulin prescription. This was derived from the 'medication' tab in EMIS, assessing both current and past medications, and from the drug history to obtain the first insulin prescription date.

4.3.4.4. Confounding baseline factors

Owing to the multiple factors that can influence diabetes progression, treatment and outcomes, it was important to take into account the effects of confounding factors for which the regression method was used. A confounder is a risk factor or exposure that is associated with the primary risk factor of interest (the independent variable e.g. depressive symptoms, diabetes distress, negative insulin beliefs) and the primary outcome of interest (the dependent variable e.g. insulin-requiring status, insulin initiation), figure 4.1. Controlling for confounding factors increases the validity of the results (Field, 2013). Failure to control for confounding factors can lead to over or underestimation of an association between the exposure and outcome. This section describes the confounding factors identified from the original SOUL-D study (baseline) for the 8-year follow-up SOUL-D study analysis.

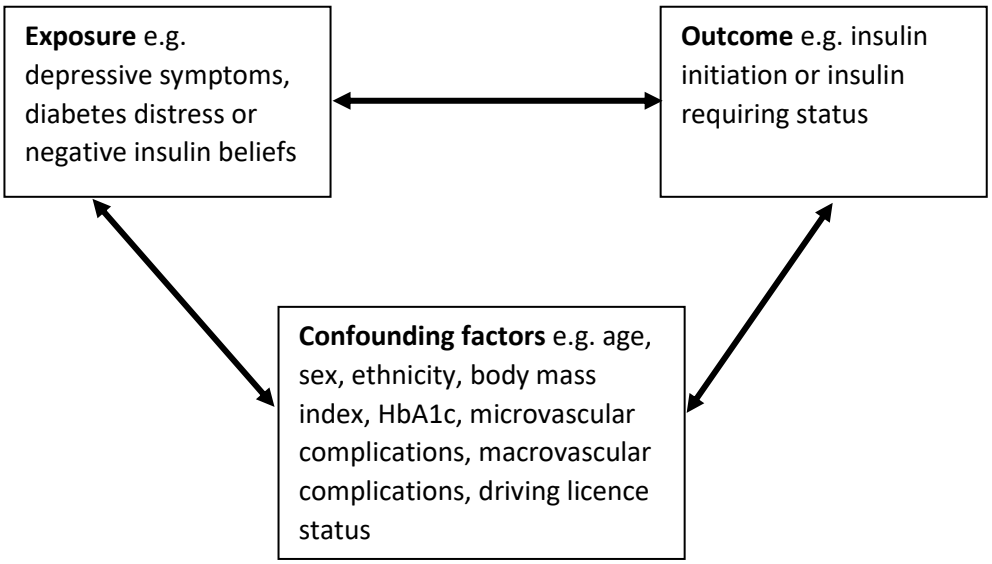

Figure 4.1-*Potential confounding factors in the SOUL-D study*

Sociodemographic factors. Age, sex, and ethnicity were obtained through self-report questionnaires, based on the 2001 UK Census (ONS, 2001).

Body mass index. Height and weight measurements were used to calculate body mass index (weight (kg)/height(m)^2).

Glycaemic levels. Glycaemic levels were measured in % by a HbA1c serum blood sample using high performance liquid chromatography (HPLC) (Premier 9210 analyser, Menarini, Italy).

Macrovascular complications. Macrovascular complications were identified by self-report and validated by medical records and included a history of myocardial infarction; coronary artery bypass graft; cerebrovascular accident; and carotid or limb re-vascularisation. Macrovascular complications were coded as present or absent.

Microvascular complications. Microvascular complications included neuropathy, retinopathy, or nephropathy. A neurothesiometer (Scientific Laboratory Supplies, Wilford, Nottingham) was used to measure neuropathy by measuring the vibration perception threshold (VPT) on the first toe of both feet and asking when the person with diabetes could feel the vibration. This was repeated 3 times and the lowest voltage was recorded. A >25 voltage indicated significant sensory neuropathy and at risk of diabetic foot ulcers (Edmonds & Foster, 2014). Urinary ACR was used as a measure of nephropathy, ratios of ≥3 indicated positive for microalbuminuria. Retinopathy was assessed through local hospital Diabetes Eye Complication Screening service using two-field photography (NHS, 2007) and coded using English Retinopathy Minimum grading system (ENSPDR, 2019). Microvascular complications were coded as present or absent.

Driving licence status. Driving licence status was identified through self-report and coded as yes or no for categories of the status.

Table 4.1-*8-year follow-up SOUL-D exposure and outcome factors*

Factors	How measured	Cut off points for categorical data
Depressive symptoms	PHQ-9 questionnaire	≥10 score= depressive symptoms
Diabetes distress	PAID questionnaire	≥40 score= high diabetes distress
Insulin beliefs	BIT questionnaire	≥5.57 score = high negative insulin beliefs
Age	Self-report	n/a
Sex	Self-report	Male/Female
Ethnicity	Self-report	White/non-white
Body mass index	Height/weight measurements	n/a
HbA1c	Serum blood sample	n/a
Macrovascular complications	Self-report/medical records	Present/absent
Microvascular complications:	Physical examination/medical records	Present/absent for neuropathy, retinopathy or nephropathy
Neuropathy	Neurothesiometer	>25 VPT voltage= sensory neuropathy
Retinopathy	DECS: two-field photography	Present/absent
Nephropathy	Urinary ACR	Ratio ≥3 =positive for microalbuminuria= Present
Insulin initiation	Medical records (insulin prescription)	Yes/No
Insulin requiring status	Medical records (information regarding number of OADs and HbA1c measurements)	Yes/No

4.3.5. Procedure

Potential participants for the original SOUL-D study were identified by general practice staff or the clinical diabetes team by medical record search strategy using diagnosis and medication prescription codes. The search strategy was tested extensively before being implemented in every surgery in EMIS. People with type 2 diabetes who consented to be contacted by the clinical team were invited by a research assistant for the original SOUL-D study assessment.

Before an 8-year follow-up SOUL-D medical record data collection commenced, the original SOUL-D study consent forms were reviewed to identify those participants who had given written consent for a 20-year medical record follow-up. General practice managers in primary care were contacted via email to invite them to participate in the 8-year follow-up SOUL-D study. If there was no response by email, the research team contacted practice managers on the telephone. The first general practice surgeries who were contacted were those who were recruited first to original SOUL-D study to maximise follow-up time. The research team had NHS research passports to allow access to surgeries in south London.

Once general practices agreed to take part in the 8-year follow-up SOUL-D study, room bookings were made at the surgery to use a computer and gain access to EMIS for medical record screening. Some surgeries allowed the research team to use surgery computers in admin rooms or reception. Medical records for the SOUL-D participants were accessed via EMIS. Unique EMIS logins for the study were generated at each individual surgery. An initial EMIS screening determined whether the participants were active, deceased, or inactive. If participants were active, all relevant information to determine insulin initiation and insulin-requiring status could be obtained, and data was entered into the Microsoft excel data collection schedule. If participants were deceased, medical record data were obtained up to date of death, EMIS would only indicate the participant had deceased if they had died whilst being a patient at that surgery (i.e. were active at the surgery at the date of death). If the participant was inactive, then as much information was obtained as possible up to the date the participant left the surgery. This was sometimes enough to obtain data for insulin-related outcomes. For inactive participants, a private company called Capita who runs Primary Care Support England (PCSE) were contacted and could trace participants' current general practice addresses who resided in England. This data could only be exchanged on receipt of NHS numbers, full name, date of birth, previous general practice address, and proof of consent. Once inactive participants could be traced to their current surgery, participants' medical records could be viewed at that surgery they moved to if accessible to the research team (i.e. in south London at this stage).

4.3.6. Statistical analysis

4.3.6.1. Data management

All data was entered into the Microsoft Excel data collection schedule before being converted into STATA 15 (StataCorp, 2017) for analysis.

4.3.6.2. Original SOUL-D versus 8-year follow-up SOUL-D characteristics

SOUL-D study baseline characteristics (age, sex, ethnicity, body mass index, HbA1c, presence of complications, driving license status, depressive symptoms, diabetes distress, and insulin beliefs) were reported for the original SOUL-D sample (n=1735) and the sample of the 8-year follow-up SOUL-D study. Mean and standard deviations were reported for continuous variables (age, body mass index, HbA1c), and the number of participants and percentages were reported for categorical variables (sex, ethnicity, presence of complications, driving license status, depressive symptoms, diabetes distress, and insulin beliefs). T-tests (for continuous data) and Pearson chi-square tests (for categorical data) were used to compare whether the 8-year follow-up SOUL-D sample significantly differed in these baseline characteristics to the original SOUL-D cohort.

4.3.6.3. Original SOUL-D characteristics stratified by psychological factors

SOUL-D baseline characteristics were stratified by each categorical psychological baseline variable (PHQ-9, PAID, BIT), to determine any significant relationships.

4.3.6.4. Eight-year SOUL-D follow-up characteristics

For the 8-year follow-up SOUL-D characteristics, the average time to follow-up was described. Median data was presented instead of the mean where data was skewed. The number and percentage of the following were calculated for the deceased in addition to the cause of death. Mean (SD) HbA1c at follow-up was reported with the number and percentage of people who had optimal HbA1c (<58 mmol/mol) and suboptimal HbA1c (≥58 mmol/mol).

4.3.6.5. Type 2 diabetes treatment progression of 8-year follow-up SOUL-D participants

Type 2 diabetes treatment progression of the 8-year follow-up SOUL-D participants was described by reporting frequency (n and %) of people on lifestyle modifications only since type 2 diabetes diagnosis (i.e. had not been prescribed any diabetes drug treatment); the number of people prescribed 1, 2, 3, or 4 OADs only; people prescribed other injectables during the follow-up period; people who had been insulin-requiring during the follow-up period; and people who had initiated insulin (i.e. prescribed insulin treatment) during the follow-up period. The types of other injectables and insulin was reported with frequencies. The mean average number of OADs prescribed before the first insulin prescription was reported. Finally, the mean (SD) HbA1c measurement closest to pre-first insulin prescription was reported.

4.3.6.6. Survival analysis

The purpose of using survival analysis is to analyse the time to an event i.e. survival time. This thesis chapter uses survival analyses to determine: 1) time to insulin-requiring status, and 2) time to insulin initiation. Censoring in survival analysis refers to when information about survival time is incomplete or missing (the event did not occur for a participant) (Altman & Bland, 1998). Censored data is not the same a missing data, censored cases are not excluded from the analysis, their data still contributes to the time at risk ('risk of experiencing event') up to the last interval during which they were known to be alive. Censored data is not considered in other analyses such as regression or odds ratios (Ferreira & Patino, 2016). The Kaplan-Meier method of survival analysis is useful to estimate survival overtime even when data is censored or different participants are followed-up for different lengths of time (Jager, Van Dijk, Zoccali, & Dekker, 2008). The Kaplan-Meier methods shows the probability of an event at certain time intervals and helps compare two groups. In this thesis study, the Kaplan-Meier method plots survival curves for i) the presence of depressive symptoms versus no presence of depressive symptoms; ii) high diabetes distress versus low diabetes distress; iii) high negative insulin beliefs versus low negative insulin beliefs for time to insulin-related outcomes. Non-parametric log-rank tests (Bland & Altman, 2004) compared survival distributions between the original SOUL-D study psychological variable categorical groups (PHQ-9, PAID, BIT).

Mean or median survival times were reported. The median survival time is a better measure of central location than the mean due to survival times often being skewed. Outliers can have a substantial impact on the mean which distorts the mean from the center. Skewed data has a smaller effect on the median as it is not dependent on all the values of the data meaning outliers do not impact the median as much as the mean. However, the median survival time can only be plotted where the cumulative survival drops below 50 percent, where this did not happen mean survival times were reported. The survival time started from original SOUL-D study data collection (i.e. type 2 diabetes diagnosis) to time of the event (insulin-requiring and insulin initiation) (Jager et al., 2008). A sub-analysis was performed on participants who were insulin requiring using the Kaplan-Meier method to chart time from when they became insulin-requiring when they initiated insulin. If the event occurred before or at baseline (i.e. original SOUL-D study data collection), then this observation was excluded from the analysis. For censored cases, time was calculated from the original SOUL-D study data collection to date of follow-up data collection. For those who had deceased by follow-up, time from the original SOUL-D study data collection to date of death was only recorded in absence of event (i.e. censored), otherwise, time to event was recorded.

The Kaplan-Meier technique is an exploratory unadjusted analysis i.e. this analysis does not allow for adjustment of confounder variables and only examined the association between independent variables (psychological factors) and time to dependent variables (insulin-requiring status and insulin initiation).

4.3.6.7. Cox regression

The Cox regression method allows for further validation of the association between exposure and time to the event by adjusting for confounders. Cox regression analyses estimated hazard ratios (HR) of time to insulin-requiring status and insulin initiation with 95% confidence intervals (CI). The estimated hazard ratio for each variable considers the other variables in the model. A hazard ratio is a test statistic of the effect of an independent variable on an outcome (dependent variable) over time.

If all assumptions were met (see the section below), a Cox regression model included the following variables: age, sex, ethnicity, body mass index, HbA1c, microvascular complications, macrovascular complications, driving license status, depressive symptoms, diabetes distress, insulin beliefs. The Cox regression model used a maximum of 10 events per variable e.g. if there were 100 insulin initiation events then the Cox regression model included 10 variables. Previous research has determined 10 events per variable was associated with estimates closest to the true value (Peduzzi, Concato, Feinstein, & Holford, 1995; Peduzzi, Concato, Kemper, Holford, & Feinstein, 1996).

4.3.6.8. Testing assumptions for Kaplan-Meier and Cox regression

The following assumptions relate to the Kaplan-Meier test and were addressed in study design:

1) **Event status is mutually exclusive.** The event status was a mutually exclusive outcome from the censored. In addition, at least one of these states must have occurred.
2) **Time to event measured precisely.** The time to event or censorship was measured at a precise time point as opposed to an interval period. This was measured in months.
3) **Left censoring avoided.** The exact point of the original SOUL-D study (i.e. baseline) measurement could be identified.

The remaining assumptions relate to Cox regression which was tested using statistical tests as described below:

4) **Proportional hazards assumptions**. This refers to a ratio of the hazards for two individuals being constant over time. The Harrell & Lee test (Schoenfeld residuals, (Lee, Harrell Jr, Tolley, & Rosati, 1983)) were also used to test this assumption, where the time-dependent covariate should be greater than 0.05. A plot of Schoenfeld residuals was also plot, where

a horizontal line in graph indicated no violation of assumption. Further, a log-log plot to test proportionality reveals no violation of the assumption if lines in the plot are parallel. If a variable violated the proportional hazards assumption, then this variable was excluded from the Cox model. If there was a continuous alternative to a categorical variable that did not violate the assumption, e.g. depressive symptoms, then this could be included in the Cox model.

5) **Deviance of residuals.** Deviance of residuals was calculated to assess for outliers (more than 3 or less than -3), this was evaluated using a two-way scatter plot.
6) **Multicollinearity.** This is where there are high intercorrelations between explanatory variables, which if used in combination in a regression model can disturb the data, and hence may not be reliable (Grewal, Cote, & Baumgartner, 2004). This assumption was tested through correlations between the 3 psychological variables (PHQ-9, PAID, BIT) were checked to see whether they were smaller than 0.8 before including them as potential confounders in Cox regression analysis.

4.3.6.9. Sample size estimation

A sample size estimation was calculated in STATA 15 based on the survival Cox regression model. The following parameters were inputted into the calculation: alpha level=0.05, power=80 percent, hazard ratio= 0.4. The variability (SD) was calculated by the difference in standard deviations of the mean in depressive symptoms between those who were on insulin versus those not on insulin at a 5-year follow-up (Keij, 2015). The power calculation was adjusted for censoring, the probability of the event was set at 0.06 as the 5-year follow-up observed around 6% were prescribed insulin injection therapy. The estimated number of events (insulin initiation) was n=38, and the estimated sample size was 624.

4.3.6.10. Missing data

Case mean substitution was used to impute missing values for the psychological measure (PHQ-9, PAID, and BIT) scores only. Case mean substitution was used at the individual participant level where there was 20% or fewer missing data per participant. For example, for the PHQ-9 there are 9 items in the questionnaire so 20% or fewer missing equates to 1 or 2 items for the individual participant missing. So, if a participant is missing 2 questions on the PHQ-9 and has a total of 14 on the remaining 7 questions, the average would be 2 for each item. This average of 2 would then be added for the remaining 2 missing items bringing the total to 18. This method imputes the missing scores based on mean scores available for that participant and assumes that the missing value is related to available data points (Raymond, 1986). An advantage of case mean substitution is it uses data provided by the same participant

to estimate own missing data, as opposed to using data from other cases in the sample. Case mean substitution is a robust method when imputing 20% missing data in random or systematic patterns (Roth, Switzer III, & Switzer, 1999).

4.4. Results

4.4.1. SOUL-D participant characteristics

4.4.1.1. Flow of participants

Figure 4.2 shows the study flowchart. The 8-year follow-up SOUL-D data collection took place between September 2017-January 2019. One thousand seven-hundred and thirty-five were screened at the original SOUL-D study and 1699 people provided consent for medical record data to be screened for 20 years. The number of records that were screened for the 8-year follow-up SOUL-D study was 1298 (from 56 surgeries) of which 1003 (out of 1699, 59.0%) records were obtained and 295 were inactive (participants had moved to a different surgery and record not yet obtained), 456 records are yet to be screened. Of the 1003 records obtained, 31 records were inactive, but enough data could be extracted for insulin-requiring status/insulin initiation (from previous active surgery).

4.4.1.2. Original SOUL-D versus 8-year follow-up SOUL-D characteristics

The baseline characteristics of the participants in this 8-year follow-up SOUL-D study (n=1003) did not statistically significantly differ from the original SOUL-D cohort (N=1735), according to age, sex, ethnicity, body mass index, HbA1c, microvascular complications, macrovascular complications, driving license status, depressive symptoms, diabetes distress and negative insulin beliefs (table 4.2). Therefore, this sample is representative of the whole cohort based on these characteristics.

4.4.1.3. Original SOUL-D study characteristics stratified by psychological factors

The original SOUL-D study characteristics were stratified by baseline categorical psychological factors (table 4.3). The presence of depressive symptoms was associated with younger age, females, higher body mass index, and presence of macrovascular symptoms. High diabetes distress was associated with to younger age, females, and non-White ethnicity. High negative insulin beliefs were associated with younger age, females, non-White ethnicity, presence of macrovascular symptoms, and driving license status.

4.4.1.4. Eight- year follow-up SOUL-D characteristics

For the 8-year follow-up SOUL-D study (n=1003), the median follow-up time was 92 months (7.67 years, IQR=80-103 months). By follow-up, 53 people had died. Reasons for death include: bowl obstruction (n=1), cancer (n=18), heart attack (n=3), liver failure (n=3), pneumonia (n=2), stroke (n=1), tumour (n=1), and information unknown from primary care records (n=24). The

mean HbA1c at follow-up was 57.29 mmol/mol (SD=17.90), with more people with optimal HbA1c (<58 mmol/mol; n=628, 62.6%) than suboptimal HbA1c (≥58mmol/mol; n=320 31.9%).

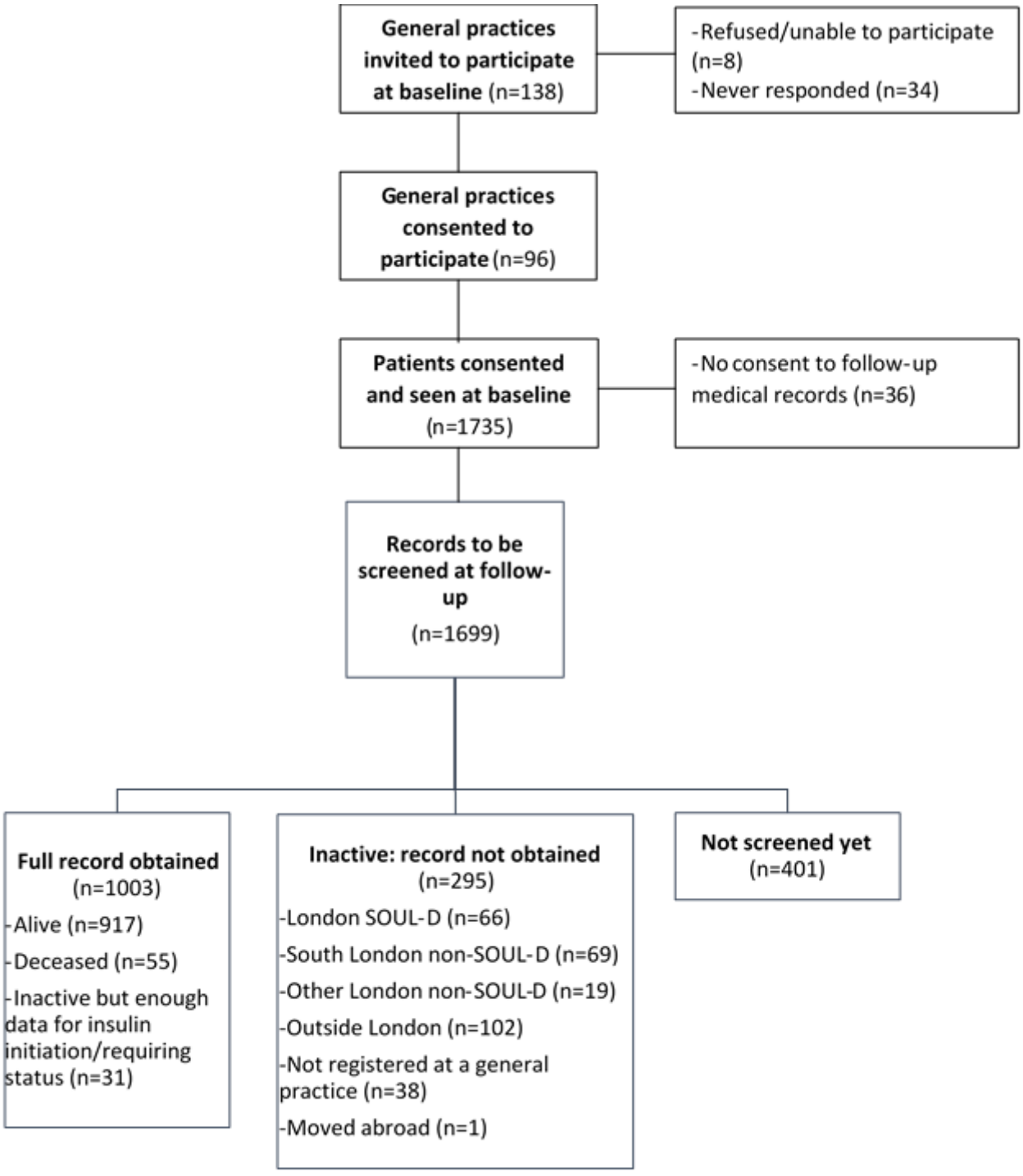

Figure 4.2- *Flow of participants in SOUL-D follow-up study*

Table 4.2-*Baseline characteristics for 8-year follow-up SOUL-D sample versus original SOUL-D cohort*

Baseline characteristic	**Total (n)[a]**	**8-year follow-up SOUL-D study (n=1003)**	**Total (n)[b]**	**Original SOUL-D cohort (n=1735)**	**Difference between samples (p-value)[c]**
Age (years), mean (SD)	963	56.63 (10.85)	1735	56.12 (11.01)	0.289
Sex, *n* (%)	1093		1735		0.780
Male		547 (54.5)		949 (54.7)	
Female		456 (45.5)		786 (45.3)	
Ethnicity, *n* (%)	963		1733		0.663
White		489 (48.8)		863 (49.8)	
Non-White		474 (47.3)		870 (50.2)	
Body mass index, mean (SD)	962	31.96 (6.43)	1732	32.00 (6.51)	0.828
Hba1c (%), mean (SD)	909	6.97 (1.39)	1620	7.01 (1.45)	0.539
Presence of microvascular symptoms, *n* (%)	804		1430		0.943
Yes		266 (26.5)		471 (32.9)	
No		538 (53.6)		959 (67.1)	
Presence of macrovascular symptoms, *n* (%)	954		1711		0.404
Yes		80 (8.4)		160 (9.4)	
No		874 (91.6)		1551 (90.6)	
Driving licence, *n* (%)	991		1709		0.420
Yes		551 (55.6)		985 (57.6)	
No		440 (44.4)		724 (42.4)	
Presence of depressive Symptoms (PHQ-9), *n* (%)	995		1714		0.944
Yes		144 (14.5)		252 (14.7)	
No		851 (85.5)		1462 (85.3)	
Diabetes Distress (PAID), *n* (%)	962		1560		0.480
High		58 (6.0)		99 (6.3)	
Low		904 (90.1)		1461 (93.7)	
Negative insulin beliefs (BIT), *n* (%)	920		1582		0.526
High		227 (22.6)		408 (25.8)	
Low		693 (69.1)		1174 (74.2)	

[a] There are missing data for some variables in the 8-year follow-up SOUL-D sample resulting in different percentages; the total number of individuals for each variable is therefore given.

[b] There are missing data for some variables in the original SOUL-D sample resulting in different percentages; the total number of individuals for each variable is therefore given.

[c] Continuous data were compared using t-tests; categorical variables were compared using χ^2 tests.

Table 4.3- *The original SOUL-D sociodemographic and diabetes characteristics stratified by psychological variables at baseline*

Baseline variable	**No depressive symptoms**	**Presence of depressive symptoms**	**P-value**	**Low diabetes distress**	**High diabetes distress**	**P-value**	**Low negative insulin beliefs**	**High negative insulin beliefs**	**P-value**
Age			**p<0.001***			**p<0.001***			**p=0.002***
N	1462	252		1460	98		1173	407	
M(SD)	56.72 (11.07)	53.08 (10.30)		56.76 (10.90)	49.78 (11.01)		56.73 (11.06)	54.74 (11.05)	
Sex, n(%)			**p=0.01***			**p=0.001**			**p<0.001***
Male	819 (56.0)	119 (47.2)		823 (56.4)	39 (39.8)		694 (59.2)	187 (45.9)	
Female	643 (44.0)	133 (52.8)		637 (43.6)	59 (60.2)		479 (40.8)	220 (54.1)	
Ethnicity, n(%)			**p=0.65**			**p<0.001***			**p<0.001***
White	736 (50.4)	123 (48.8)		770 (52.7)	32 (32.7)		692 (59.0)	113 (27.8)	
Non-White	725 (49.6)	129 (51.2)		690 (47.3)	66 (67.3)		481 (41.0)	294 (72.2)	
Body mass index			**p<0.001***			**p=0.40**			**p=0.99**
N	1459	252		1457	98		1171	406	
M(SD)	31.78 (6.34)	33.34 (7.26)		31.95 (6.55)	32.52 (5.84)		32.01 (6.47)	32.00 (6.48)	
HbA1c			**p=0.13**			**p=0.89**			**p=0.71**
N	1370	236		1371	92		1108	373	
M(SD)	6.98 (1.46)	7.14 (1.44)		6.95 (1.37)	7.26 (1.67)		6.97 (1.44)	7.13 (1.57)	
Presence of microvascular complications, n(%)			**p=0.33**			**p=0.69**			**p=0.48**
Yes	390 (32.3)	74 (35.7)		405 (33.4)	24 (31.2)		321 (33.3)	110 (31.3)	
No	818 (67.7)	133 (54.3)		807 (66.6)	53 (68.8)		643 (66.7)	242 (68.8)	
Presence of macrovascular complications, n(%)			**p=0.01***			**p=0.56**			**p=0.02***
Yes	125 (8.7)	34 (13.7)		129 (9.0)	7 (7.2)		120 (10.4)	26 (6.5)	
No	1317 (91.3)	214 (86.3)		1310 (91.0)	90 (92.8)		1039 (89.6)	374 (93.5)	
Driving licence status, n(%)			**p=0.14**			**p=0.26**			**p<0.001***
Yes	840 (58.4)	133 (53.4)		845 (58.6)	50 (52.6)		724 (62.6)	186 (46.2)	
No	599 (41.6)	166 (46.6)		598 (41.4)	45 (47.4)		432 (37.4)	217 (53.8)	

4.4.1.5. Type 2 diabetes treatment progression of 8-year follow-up SOUL-D participants

Nearly fifteen percent of the 8-year follow-up SOUL-D study participants were on lifestyle modifications only since type 2 diabetes diagnosis (n=147) and were not prescribed any diabetes drug treatment. Within the 8-tear follow-up period, most people were prescribed 1 OAD only (n=391), n=205 were prescribed 2 OADs only, n=91 were prescribed 3 OADs only, and n=9 were prescribed 4 OADs only.

Forty-eight people (4.8%) were treated with other injectables (GLP-1 RAs) at some point during the follow-up period including exenatide (n=4), liraglutide (n=27), dulaglutide (n=16), and insulin degludec plus liraglutide (n=1).

Three-hundred and forty-one people (34.0%) were insulin-requiring during the follow-up period i.e. were on 2 or more OADs despite suboptimal HbA1c (>58 mmol/mol).

Ninety-six people (9.6%) initiated insulin within the follow-up period, most starting on one type of insulin (n=92), n=4 on 2 types of insulin, table 4.4. The most common starting insulin was intermediate-acting insulin (NPH; n=47, 49.0%). The most common number of OADs prescribed before the first insulin prescription was 2 (Mean=1.75, SD=0.88). The HbA1c measurement closest to pre-first insulin prescription was on average suboptimal (Mean=85.41, SD=26.27).

4.4.2. Insulin requiring status

Forty-one observations were excluded from analysis owing to insulin-requiring occurring on or before the original SOUL-D study data collection (baseline), hence 962 observations remained. More people had not been insulin-requiring during the follow-up period (n=620) than those who had been insulin-requiring (n=341). The overall median time to insulin-requiring status was 80 months (range 1-125), around 6.67 years.

A Kaplan-Meier survival estimate curve (figure 4.3) shows a steady increase in insulin-requiring events up to 110 months where the number of events then remains static.

4.4.2.1. Survival distribution for insulin-requiring status by depressive symptoms: non-parametric comparison

On average, those who had depressive symptoms at baseline required insulin earlier (n=140, Mean=68.81 months, SD=32.30) than those who did not have depressive symptoms (n=814, Mean=75.09 months, SD=28.28) by about 7 months, figure 4.4. A log-rank test revealed a statistically significant difference in survival distribution between the two groups, $\chi 2(1) = 8.54$, p=0.003.

Table 4.4- *Frequency of starting insulins of SOUL-D participants (n=96)*

Starting insulin treatment	**n (%)**
Intermediate acting insulin	
NPH	47 (49.0)
Long acting	
Insulin glargine	14 (14.6)
Insulin determir	4 (4.2)
Humulin M3	1 (1.0)
Toujeo	1 (1.0)
Fast-acting insulin	
Insulin aspart	4 (4.2)
Soluble insulin	1 (1.0)
Pre-mixed insulin	
Humalog Mix 50	1 (1.0)
NovoMx 30	18 (18.8)
Insulatard	1 (1.0)
Combination of starting insulin	
Insulin aspart and NovoMx 30	1 (1.0)
Insulin aspart and NPH	1 (1.0)
Insulin aspart and insulin glargine	1 (1.0)
NovoMx 30 and humulin M3	1 (1.0)
Total	96

4.4.2.2. Survival distribution for insulin-requiring status by diabetes distress: non-parametric comparison

On average, those who had high diabetes distress at baseline required insulin earlier (n=55, Mean=67.02 months, SD=32.77) than those with low diabetes distress (n=866, Mean=74.52 months, SD=28.41) by about 7 months, figure 4.5. A log-rank test revealed there was no statistically significant difference in survival distribution between the two groups, $\chi2(1) = 1.11$, $p=0.29$.

4.4.2.3. Survival distribution for insulin-requiring status by negative insulin beliefs: non-parametric comparison

On average, those who had high negative insulin beliefs at baseline required insulin earlier (n=216, Mean=72.59 months, SD=29.98) than those with low negative insulin beliefs (n=663, Mean=74.96 months, SD=28.72) by about 2 months, figure 4.6. A log-rank test revealed there was no statistically significant difference in survival distribution between the two groups, $\chi2(1) = 2.23$, $p=0.14$.

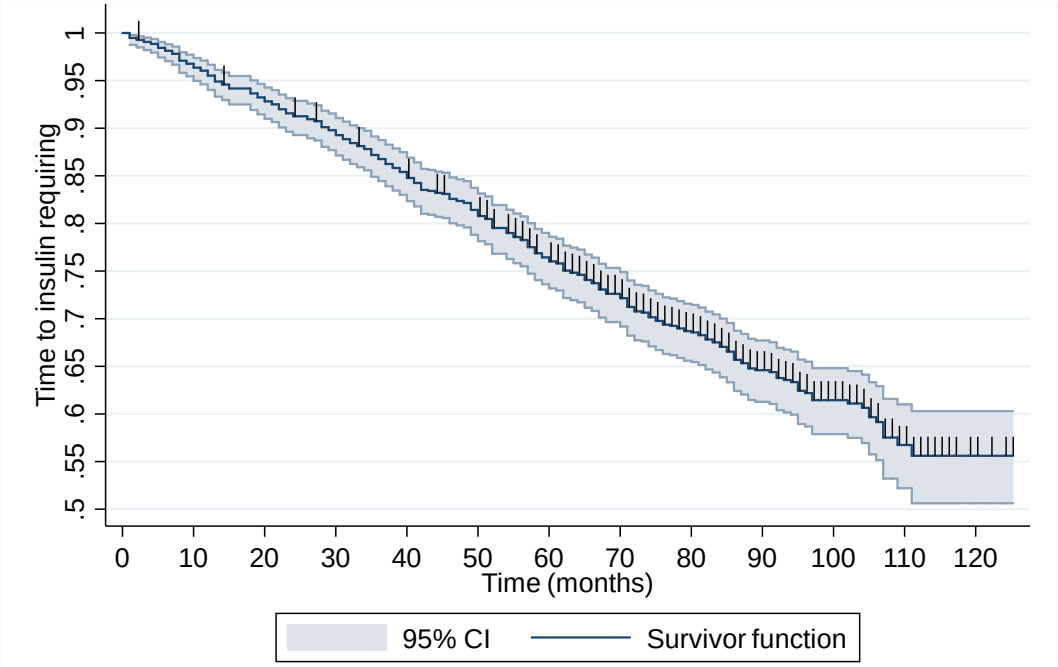

Figure 4.3- *A Kaplan-Meier survival estimate curve for time to insulin requiring status in the SOUL-D cohort*

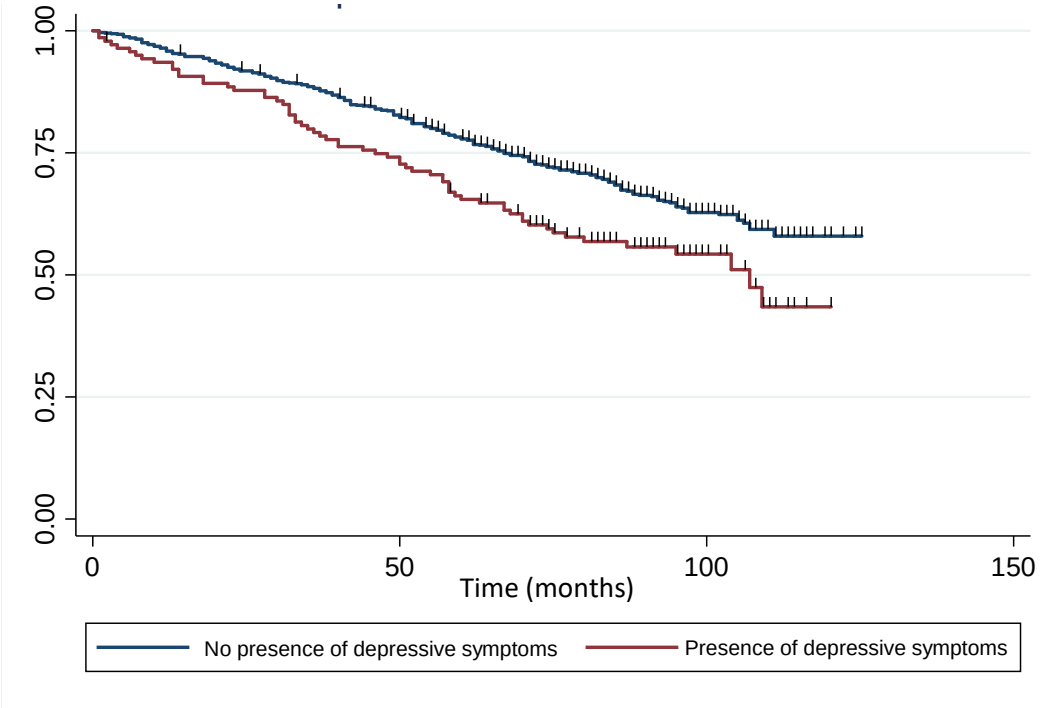

Figure 4.4- *Kaplan-Meier survival distribution for depressive symptom groups for time to insulin requiring status in the SOUL-D cohort*

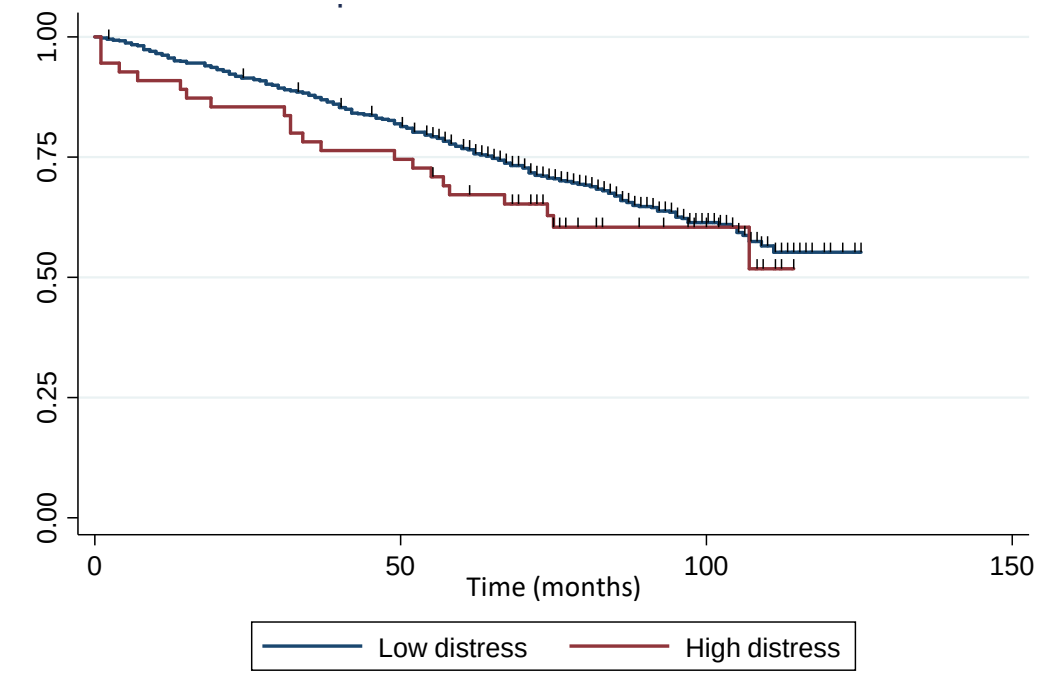

Figure 4.5- *Kaplan-Meier survival distribution for diabetes distress groups for time to insulin requiring status in the SOUL-D cohort*

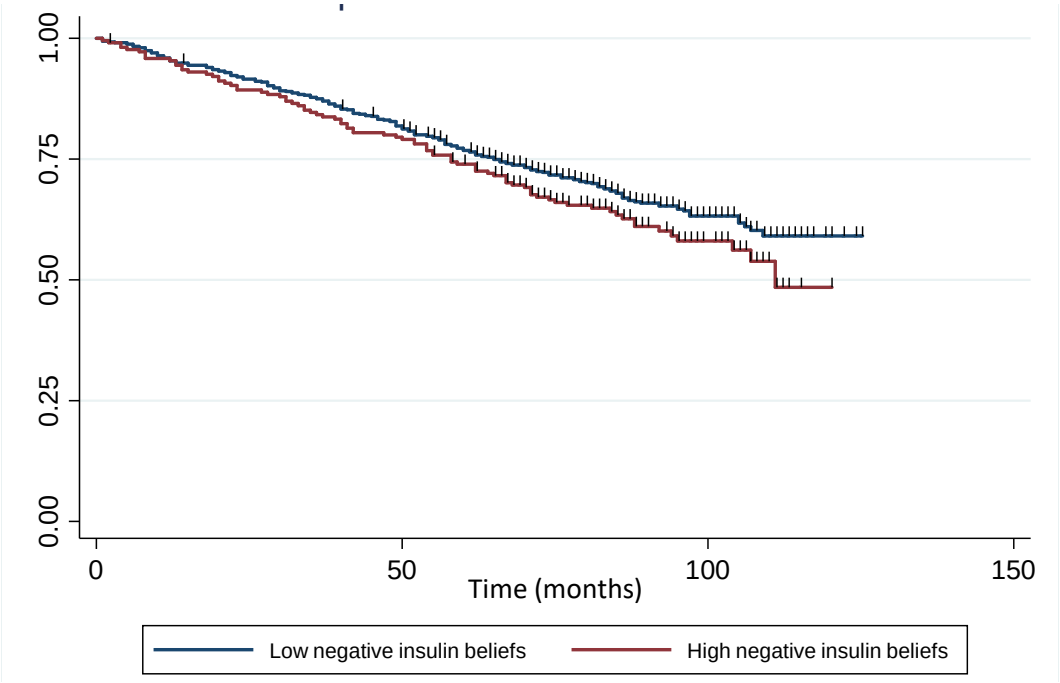

Figure 4.6- *Kaplan-Meier survival distribution for negative insulin beliefs groups for time to insulin requiring status in the SOUL-D cohort*

4.4.2.4. Testing assumptions for Cox regression

There was 341 insulin-requiring events, 11 variables were included in the Cox regression model: age, sex, ethnicity, depressive symptoms, diabetes distress, insulin beliefs, body mass index, macrovascular complication status, microvascular complication status, HbA1c, and driving licence status.

On testing the proportional hazards assumption, microvascular complications (categorical variable) was statistically significant (p=0.01) and therefore violates the assumption. All other variables were not statistically significant. However, a plot of Schoenfeld residuals reveals a nearly horizontal line in the graph indicating there is no violation of the proportional hazard's assumption, figure 4.7. In addition, a log-log plot to test proportionality shows the lines in the plot are parallel which indicates this variable does not violate the assumption (figure 4.8). Therefore, the microvascular complications variable was included in the Cox regression model.

The deviance residuals were calculated to assess for outliers (more than 3 or less than -3). A two-way scatter plot shows there are no outliers, figure 4.9.

There was no evidence of multicollinearity between baseline psychological variables. Even though these variables were all statistically significantly associated with one another (table 4.5), the regression coefficients were less than 0.80. Therefore, all three psychological factors could be included as independent variables in the Cox regression analyses.

Table 4.5-*Intercorrelations for the original SOUL-D explanatory psychological variables*

Baseline psychological variables	**PHQ-9**	**PAID**	**BIT**
PHQ-9	1	0.30**	0.06*
PAID	0.30**	1	0.14**
BIT	0.06*	0.14**	1

**. Correlation is significant at the 0.01 level (2-tailed).

*. Correlation is significant at the 0.05 level (2-tailed).

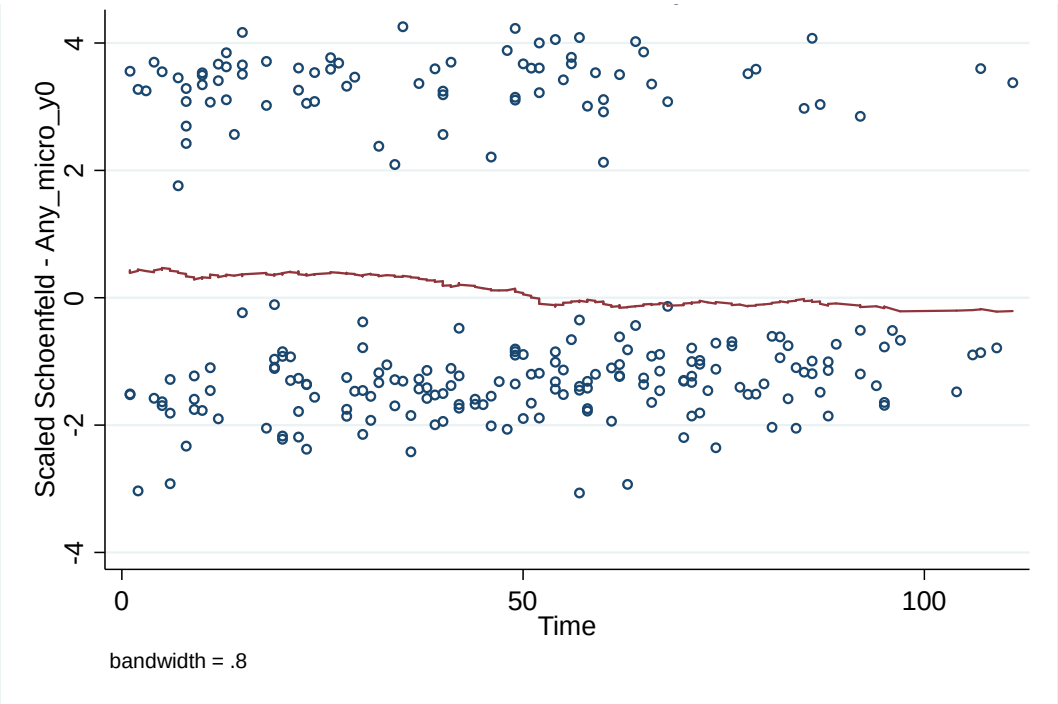

Figure 4.7- *Test of proportional hazards assumption for insulin requiring status in the SOUL-D cohort*

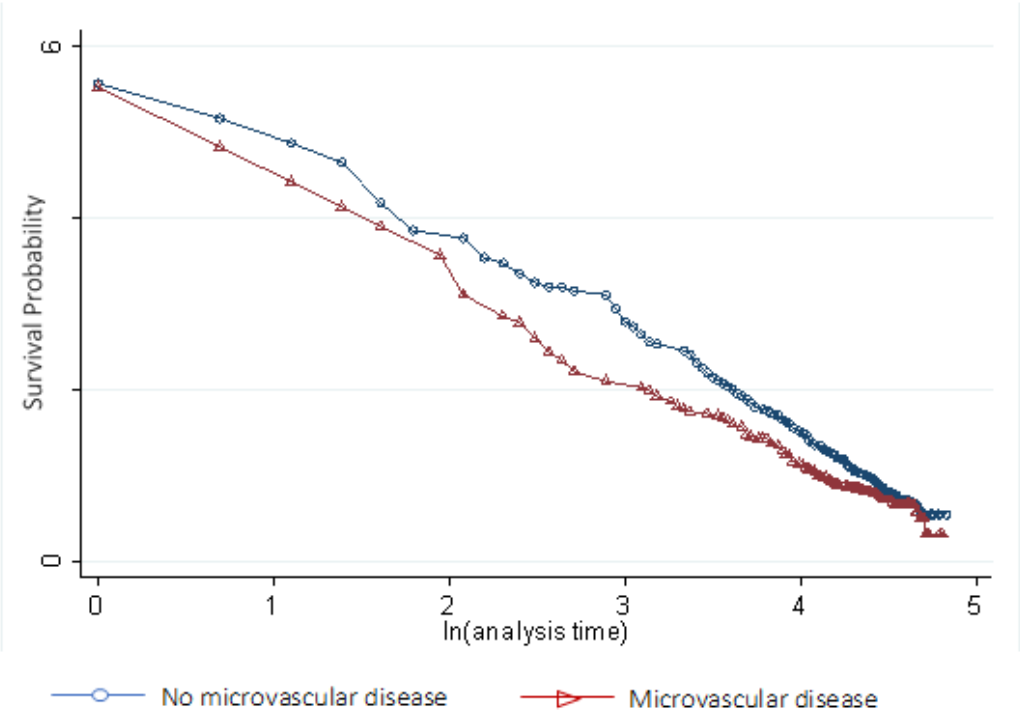

Figure 4.8- *Log-log plot to test proportional hazards for insulin requiring status in the SOUL-D cohort*

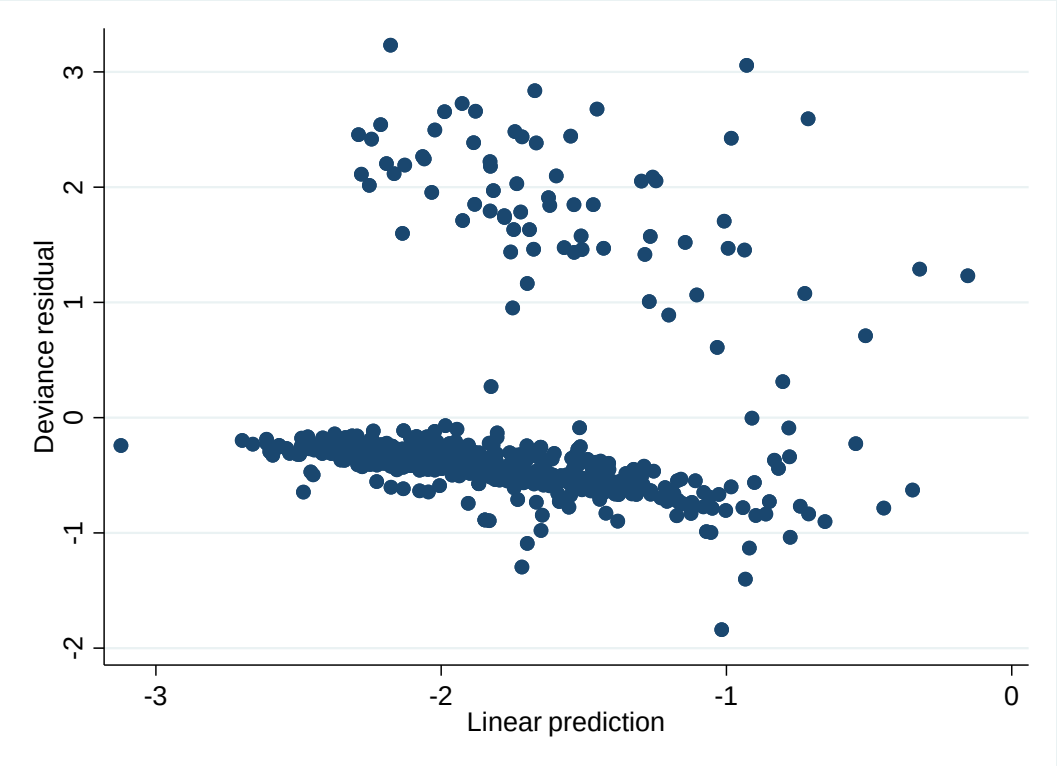

Figure 4.9- *Deviance residuals plot to assess outliers in Cox regression for insulin requiring status in the SOUL-D cohort*

4.4.2.5. Cox regression: insulin-requiring status

Two independent variables made a unique statistically significant contribution to the model (age and HbA1c), controlling for all other variables, table 4.6. People with higher HbA1c (HR=1.38, 95% CI=1.29-1.47, p<0.001) and younger age (HR=0.97, 95% CI=0.96-0.98, p<0.001) at baseline were more likely to be insulin-requiring within the follow-up period.

4.4.3. Insulin initiation

Thirty-six observations were excluded from the analysis owing to insulin initiation commencing before baseline, hence 967 observations remained. More people had not been prescribed insulin during the follow-up period (n=871) than those who had been prescribed insulin (n=96). The overall median time to insulin initiation was 89 months (IQR=75-103 months), around 7.17 years.

A Kaplan-Meier survival estimate curve (figure 4.10) shows that after 95 months (7.92 years) there was a more rapid increase in insulin initiation events, and after around 110 months the number of events remains static.

Table 4.6- *Cox regression for insulin requiring status in SOUL-D cohort*

Baseline	Hazard ratio	Standard error	Sig.	95.0% CI	
				Lower	Upper
Age at baseline	0.97	0.01	<0.001	0.96	0.98
Sex (female)	1.02	0.15	0.87	0.77	1.36
Ethnicity (non-white)	0.89	0.13	0.44	0.66	1.20
Depressive symptoms (Depressive symptoms)	1.34	0.24	0.10	0.95	1.91
Diabetes distress (High)	0.74	0.23	0.33	0.40	1.36
Negative insulin beliefs (High)	1.17	0.18	0.30	0.87	1.59
Body mass index	1.00	0.01	0.69	0.98	1.02
Macrovascular complication (present)	1.00	0.28	0.99	0.59	1.72
Microvascular complications (present)	1.41	1.16	0.35	0.87	1.50
HbA1c	1.38	0.04	<0.001	1.29	1.47
Driving licence (yes)	1.15	0.16	0.30	0.88	1.52

4.4.3.1. Survival distribution for insulin initiation by depressive symptoms: non-parametric comparison

On average, those who had depressive symptoms at baseline initiated insulin earlier (n=140, Mean= 83.27 months, SD=23.98) than those who did not have depressive symptoms (n=817, Mean=86.34 months, SD=20.88) by about 3 months, figure 4.11. A log-rank test revealed a statistically significant difference in survival distribution between the two groups, $\chi2(1) = 17.81$, $p < 0.001$.

4.4.3.2. Survival distribution for insulin initiation by diabetes distress: non-parametric comparison

On average, those who had high diabetes distress at baseline initiated insulin earlier (n=59, Mean=77.42 months, SD=26.08) than those with low diabetes distress (n=866, Mean=86.27 months, SD=20.64) by about 9 months, figure 4.12. A log-rank test revealed a statistically significant difference in survival distribution between the two groups, $\chi2(1) = 8.54$, $p=0.003$.

4.4.3.3. Survival distribution for insulin initiation by negative insulin beliefs: non-parametric comparison

On average, those who had high negative insulin beliefs at baseline initiated insulin earlier (n=222, Mean=85.41 months, SD=20.53) than those with low negative insulin beliefs (n=659, Mean=86.46 months, SD=21.59) by about 1 month, figure 4.13. A log-rank test

revealed there was no statistically significant difference in survival distribution between the two groups, $\chi 2(1) = 1.00$, $p=0.32$.

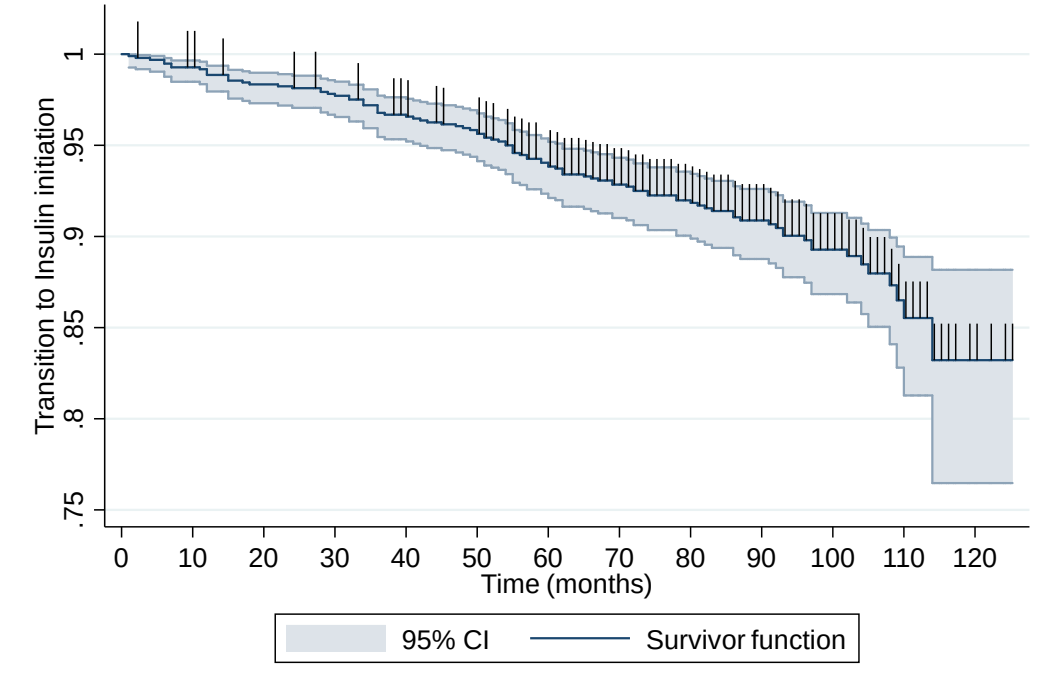

Figure 4.10- *A Kaplan-Meier survival estimate curve for time to insulin initiation in the SOUL-D cohort*

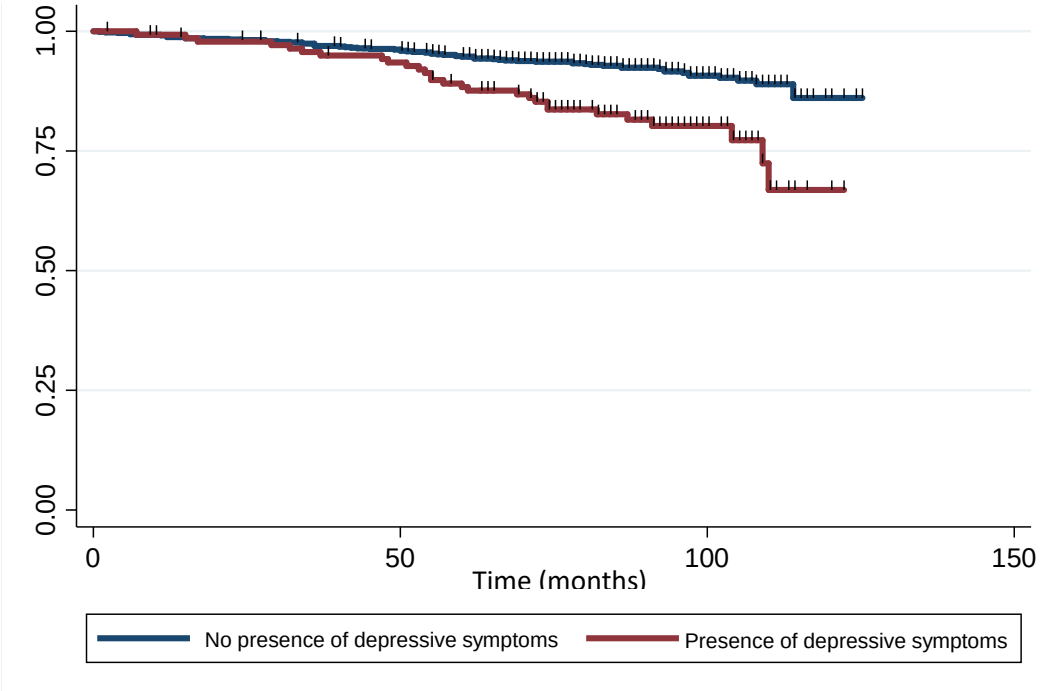

Figure 4.11- *Kaplan-Meier survival distribution for depressive symptom groups for time to insulin initiation in the SOUL-D cohort*

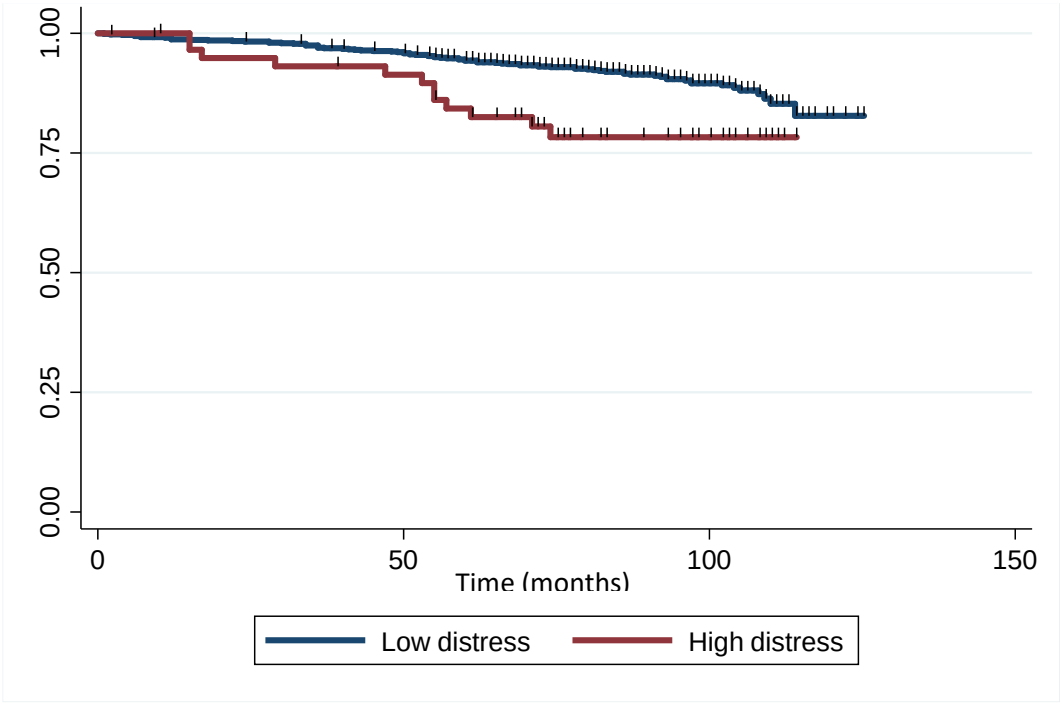

Figure 4.12- *Kaplan-Meier survival distribution for diabetes distress groups for time to insulin initiation in the SOUL-D cohort*

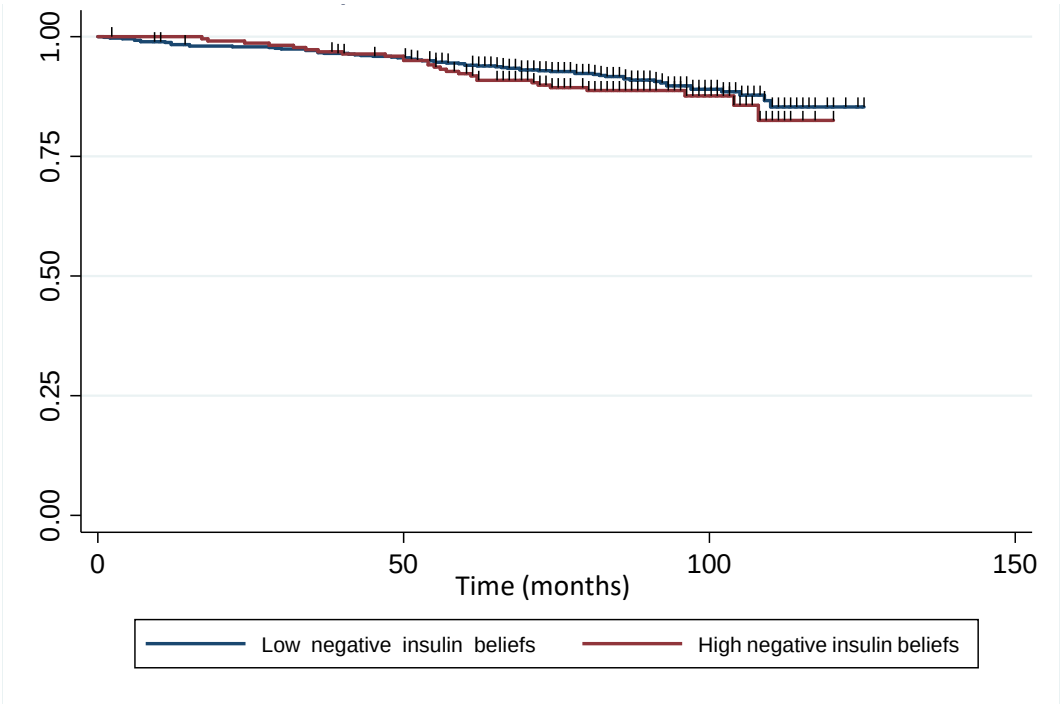

Figure 4.13- *Kaplan-Meier survival distribution for negative insulin belief groups for time to insulin initiation in the SOUL-D cohort*

4.4.3.4. Testing assumptions for Cox regression

There were 96 insulin initiation events, hence a maximum of 10 variables were included in the Cox regression model: age, sex, ethnicity, depressive symptoms, diabetes distress, insulin beliefs, body mass index, macrovascular complication status, microvascular complication status, and HbA1c. On testing the proportional hazards assumption, depressive symptoms as a categorical variable was statistically significant (p=0.02) and violated the proportional hazards assumption, however, depressive symptoms as a continuous variable was not statistically significant (p=0.15), hence not violating the proportional hazards assumption. Therefore, depressive symptoms as a continuous variable does not violate the proportional hazards assumption and was included in the Cox regression model. All other variables were not statistically significant and therefore do not violate this assumption. Further, a plot of Schoenfeld residuals reveals a nearly horizontal line in the graph indicating there is no violation of the proportional hazard's assumption, figure 4.14.

The deviance residuals were calculated to assess for outliers (> 3 or < -3). A two-way scatter plot shows there are no outliers, figure 4.15.

There was no evidence of multicollinearity between baseline psychological variables. Even though these variables were all statistically significantly associated with one another (table 4.5), the regression coefficients were less than 0.80. Therefore, all three psychological variables could be included as independent variables in Cox regression analyses.

4.4.3.5. Cox regression: insulin initiation

Four independent variables made a unique statistically significant contribution to the model (age, depressive symptoms macrovascular complications, and HbA1c), controlling for all other variables, table 4.7. People who had a macrovascular complication at baseline were 2.4 times more likely to initiate insulin within the follow-up period (HR=2.40, 95% CI=1.13-5.08, p=0.02) than those without macrovascular complications. People with higher depressive symptom scores (HR=1.06, 95% CI=1.02-1.10, p=0.005), higher HbA1c (HR=1.26, 95% CI=1.11-1.42, p<0.001) and younger age (HR=0.96, 95% CI=0.93-0.98, p<0.001) at baseline were more likely to initiate insulin within the follow-up period.

4.4.4. Time from insulin-requiring to insulin initiation

The mean time from being insulin-requiring to starting insulin (n=55) was 31.22 months (SD=18.63), around 2.5 years.

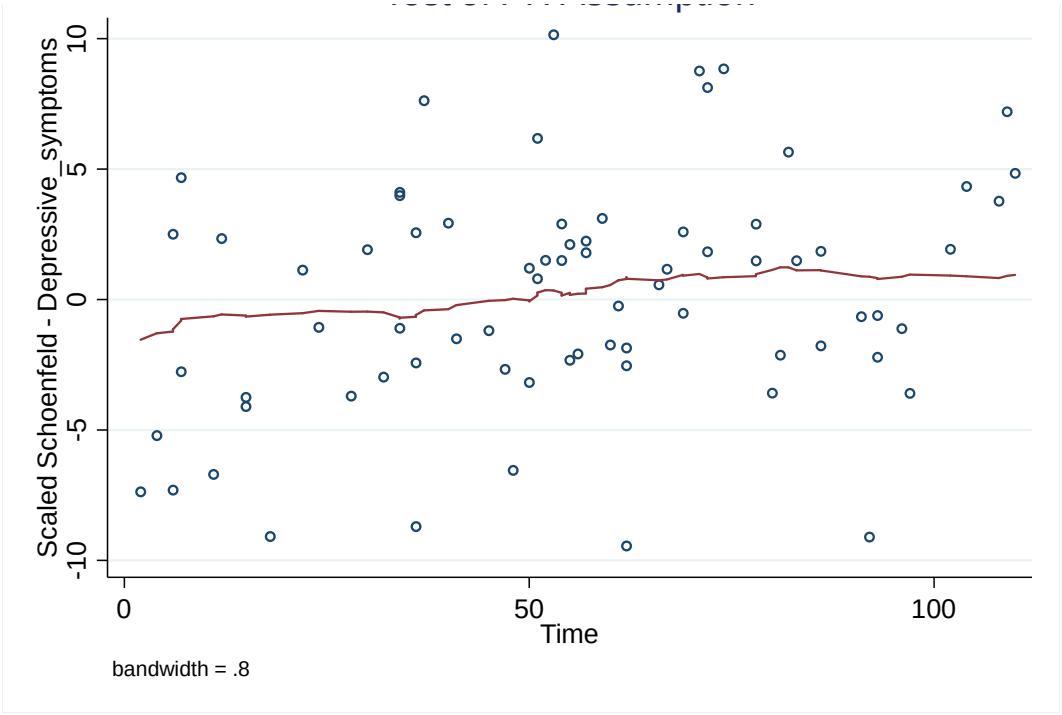

Figure 4.14- *Test of proportional hazards assumption for insulin initiation in the SOUL-D cohort*

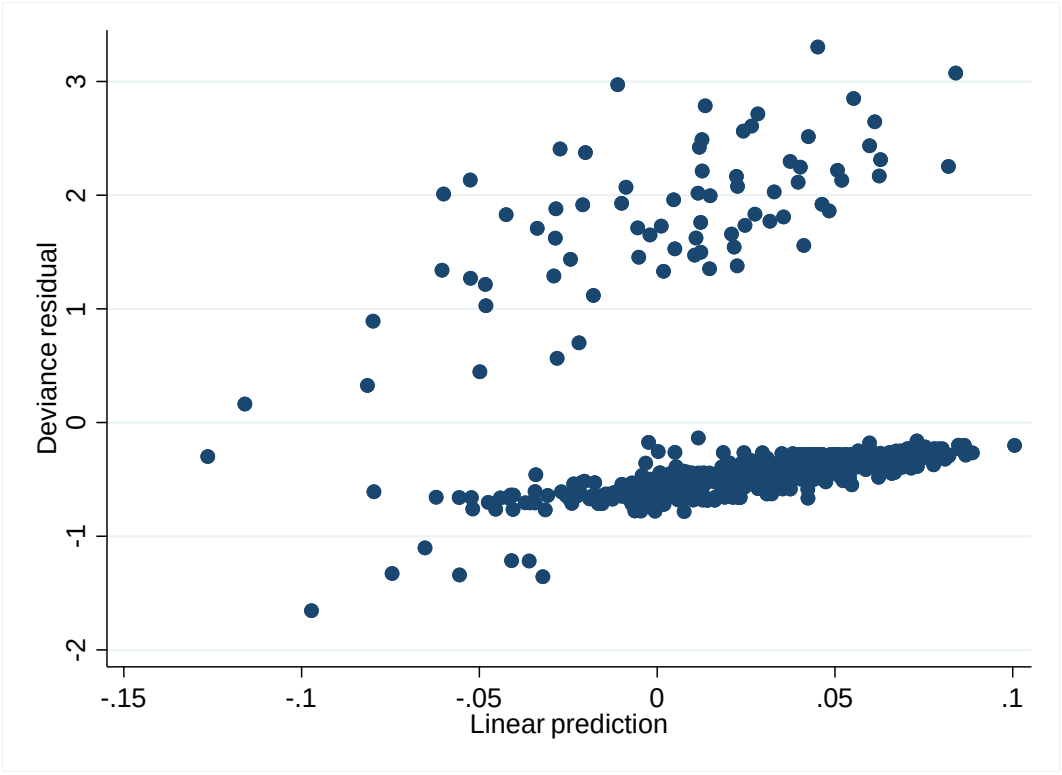

Figure 4.15-*Deviance residuals plot to assess outliers for Cox regression for insulin initiation in the SOUL-D cohort*

Table 4.7- *Cox regression for insulin initiation in the SOUL-D cohort*

Baseline variables	Hazard ratio	Standard error	Sig.	95.0% CI	
				Lower	Upper
Age at baseline	0.96	0.01	<0.001	0.93	0.98
Sex (female)	1.25	0.33	0.40	0.75	2.11
Ethnicity (non-white)	0.71	0.19	0.21	0.42	1.21
Depressive symptoms (continuous)	1.061	0.56	0.005	1.02	1.10
Diabetes distress (High)	1.23	0.54	0.64	0.52	2.90
Negative insulin beliefs (High)	1.35	0.38	0.28	0.78	2.34
Body mass index	0.96	0.02	0.06	0.92	1.00
Macrovascular complication (present)	2.40	0.92	0.02	1.13	5.08
Microvascular complications (present)	1.00	0.26	0.99	0.61	1.66
HbA1c	1.26	0.08	<0.001	1.11	1.42

4.5. Discussion

This was a prospective cohort study of an 8-year follow-up of an incident cohort of people with type 2 diabetes (n=1735), the SOUL-D cohort. For this study n=1003 were followed up from September 2017-January 2019 in terms of accessing their medical records. Three hundred and forty-one (34.0%) people with type 2 diabetes became insulin-requiring during the follow-up period. Ninety-six people (9.6%) were prescribed insulin within the follow-up period.

4.5.1. Summary of findings: time to insulin-requiring status

The median time to insulin-requiring status in this cohort was around 6.5 years from type 2 diabetes diagnosis. Psychological factors (depressive symptoms, diabetes distress or insulin beliefs) measured at type 2 diabetes diagnosis were not associated with time to insulin-requiring status after adjusting for confounding variables (age, sex, ethnicity, body mass index, HbA1c, microvascular complications, macrovascular complications, driving license status). Factors associated with shorter time to insulin-requiring status (after adjusting for confounding) were higher HbA1c and younger age.

4.5.2. Summary of findings: time to insulin initiation

The median time to starting insulin therapy from type 2 diabetes diagnosis was around 7 years. This research was novel in exploring an 8-year prospective relationship between psychological factors (depressive symptoms, diabetes distress, and insulin beliefs) and time

to insulin initiation. People with higher depressive symptom scores at type 2 diabetes diagnosis had a statistically significantly shorter time to insulin initiation than those with lower depressive symptoms, this association remained after adjusting for confounding variables (age, sex, ethnicity, body mass index, HbA1c, microvascular complications, macrovascular complications, driving license status). Diabetes distress and negative insulin beliefs at type 2 diabetes diagnosis were not associated with time to insulin initiation after adjusting for other confounding variables. Other factors that were associated with shorter time to insulin initiation (after adjusting for confounding) included: the presence of macrovascular complications, higher HbA1c, and younger age.

4.5.3. Comparison to the literature

4.5.3.1. Insulin delay

Previous research has reported a delay of up to 5 years in starting insulin (Khunti, Damci, et al., 2012) which is longer than this 8-year follow-up SOUL-D study reporting 2.5 years between insulin-requiring status and insulin initiation.

4.5.3.2. Depressive symptoms

In an adjusted analysis, depressive symptoms were not associated with insulin-requiring status. However, in an unadjusted analysis, depressive symptoms were associated with insulin-requiring status. An explanation for this could be the baseline age or HbA1c mediates this relationship. Therefore, there is not a direct relationship between depressive symptoms at type 2 diabetes diagnosis and time to insulin-requiring status, more that depressive symptoms are associated with younger age or higher HbA1c which is associated with insulin-requiring status. Mediation analyses were not conducted in this thesis chapter.

The 8-year follow-up SOUL-D findings of an association between depressive symptoms and time to insulin initiation are contrary to previous evidence from two studies that found depressive symptoms were not associated with time to insulin initiation (Iversen et al., 2015; Nefs et al., 2013). Findings of this thesis study are based on PHQ-9 depressive symptom scores, however, Iversen et al., 2015 measured depressive symptoms via the Hospital Anxiety and Depression Scale (HADS; (Spinhoven et al., 1997)) and Nefs et al., 2013 used the Edinburgh Depression Scale (EDS; (Cox, Holden, & Sagovsky, 1987)). Previous research has indicated both HADs and PHQ-9 are both reliable and valid measures of depressive symptoms, however, the PHQ-9 identifies significantly more people with moderate or severe depression than the HADs scale (Cameron, Crawford, Lawton, & Reid, 2008). This may have contributed to the finding of an association between depressive symptoms and time to insulin initiation in this thesis study. The PHQ-9 is sensitive to

determining depressive symptoms as it has previously been validated against diagnostic interviews within the SOUL-D cohort (Twist et al., 2013). However, in this cohort, baseline depressive symptoms were associated with baseline and 2-year follow-up macrovascular complications (Ismail et al., 2017) which indicates the need to initiate insulin sooner. This is further supported by this 8-year follow-up SOUL-D analysis which found macrovascular complications were associated with shorter time to insulin initiation.

4.5.3.3. Diabetes distress

In this study, there was no association between diabetes distress and time to insulin-requiring status or insulin initiation. This is contrary to what would be expected as previous longitudinal and cross-sectional research links diabetes distress to suboptimal glycemic levels (Aikens, 2012; Gonzalez et al., 2015; Hayashino et al., 2012; Tsujii et al., 2012; Winchester et al., 2016). However, as depressive symptoms were associated with insulin initiation and diabetes distress was not associated with insulin initiation in the SOUL-D cohort, this supports previous evidence which found diabetes distress and depressive symptoms are separate constructs (Fisher et al., 2007; Gonzalez, Delahanty, Safren, Meigs, & Grant, 2008; Schmitt et al., 2014).

4.5.3.4. Negative insulin beliefs

There was no association between negative insulin beliefs at baseline and insulin-requiring status or insulin initiation. The BIT questionnaire is a validated measure of insulin beliefs (Petrak et al., 2007). However, other measures of insulin beliefs have been used in this field, for example, the Insulin Treatment Appraisal Scale (ITAS) (Snoek et al., 2007). Previous research has found that fewer negative insulin appraisals (measured using ITAS) were associated with willingness to start insulin therapy (Holmes-Truscott, Blackberry, O'Neal, Furler, & Speight, 2016), however, this was a cross-sectional study and measured behavioral attitudes as opposed to behavior (initiating insulin). Other research found an association between negative insulin beliefs and delay to insulin initiation, again this study used ITAS (Hessler et al., 2018), which could account for different findings in this thesis chapter.

4.5.3.5. Age

Elderly people with type 2 diabetes are often given higher glycemic targets due to the increased risk of hypoglycemia which can be associated with cognitive impairment, accidents, and hospital admissions (Sinclair, Abdelhafiz, Forbes, & Munshi, 2019; Sinclair et al., 2012). In addition, some elderly people may have a functional limitation which means they are unable to self-administer insulin (Yakaryılmaz & Öztürk, 2017). These factors

contribute to elderly people with type 2 diabetes being less likely to be prescribed insulin therapy, which is consistent with findings of younger age being associated with shorter time to insulin initiation in this thesis chapter. In addition, it was found younger age was associated with insulin-requiring status. This falls in line with previous research that people diagnosed in older age have better glycemic levels than those diagnosed at a younger age (Benoit, Fleming, Philis-Tsimikas, & Ji, 2005; Huang, 2016), therefore if younger people have higher glycemic levels then they could require insulin sooner.

4.5.3.6. HbA1c

NICE guidelines recommend starting insulin when despite dual OAD therapy, HbA1c is above 58mmol/mol (NICE, 2009), to prevent long-term diabetes complications. The findings of this thesis chapter appear to suggest that NICE guidance is followed as those with higher HbA1c at type 2 diabetes diagnosis initiated insulin sooner. However, in In this cohort the average pre-insulin initiation HbA1c was above 58 mmol/mol (Mean=85.41, SD=26.27), which falls in line with other research which found despite clinical need people delay insulin initiation (Khunti, Damci, et al., 2012; Rubino et al., 2007; Zografou et al., 2014).

4.5.4. Strengths and limitations

A limitation of cohort design is the observational nature, therefore causation cannot be inferred, only association, as it is not possible to control for all factors that relate to the outcome. However, observational research can inform future clinical trials where causation can be determined. The strength of a prospective cohort design is that it allows for an estimation of time to an event eliminating the risk of recall bias, and it is possible to estimate the population at risk of an outcome.

It is important to follow up as many participants as possible from baseline to reduce the risk of biased results, as the reason for the loss of participants might be related to the exposure or outcome. Not all participants from the original SOUL-D cohort were followed-up in this 8-year follow-up SOUL-D study, and bias may have been introduced in the selection of participants followed up from certain surgeries or only following up those who still reside in south London. There were no statistically significant differences in baseline characteristics between the original SOUL-D sample (n=1735) and the 8-year follow-up SOUL-D sample (n=1003) analysed in this report indicting bias was minimised. In addition, this 8-year follow-up SOUL-D sample was powered, the sample size estimation was n=624 (80% power, 0.05 alpha level), this study followed-up up n=1003.

The point at which a person was insulin-requiring might not be the exact point as it was based on the available HbA1c values from the participants' medical record. For example, for some, it could have been 6 months since the last HbA1c test and therefore they could have been requiring at any point over that time. This means the true time to insulin-requiring status could not be determined. The definition of insulin-requiring for this analysis was according to NICE guidelines (2 OADs plus HbA1c >58mmol/mol), however, NICE guidelines also recommend setting individualised targets based on other factors such as comorbidities, personal preferences etc. This might account for why a proportion of people were coded as 'insulin-requiring' (according to this definition) but did not initiate insulin.

In this 8-year follow-up SOUL-D study, the date of insulin initiation was defined as the date of first insulin prescription, however, this might not be the true point of insulin initiation. For example, insulin might not have been initiated exactly on that date of the first insulin prescription or initiated at all. Additional information from the participant could confirm whether this was true i.e. asking the participants whether they did start insulin on that date or at all, however, this would rely on retrospective memory which may be inaccurate (i.e. recall bias). Therefore, the date of first insulin prescription was the best prospective measure of insulin initiation.

This thesis chapter analysis did not examine adherence or persistence to insulin therapy, without data on adherence, it cannot be determined whether participants prescribed insulin went on to administer insulin. Previous research on OAD adherence suggests that more than 50% of people do not take their medication (Donnan, MacDonald, & Morris, 2002). Therefore, when glycaemic targets are not being met (because of this poor treatment adherence) health care professionals might unnecessarily intensify their treatment (Rozenfeld, Hunt, Plauschinat, & Wong, 2008). If this translates to intensifying to insulin therapy, then this could lead to problems with adhering to this therapy. Future research with type 2 diabetes cohorts could compare prescription databases with medical records to help identify adherence issues with insulin therapy. Future research on this cohort could also ascertain whether people with type 2 diabetes and comorbid depressive symptoms are more likely to discontinue insulin therapy. Previous research found that people with type 2 diabetes and depressive symptoms are more likely to discontinue insulin within 90 days of initiation (Ascher-Svanum et al., 2014), the SOUL-D cohort has the potential to analyse discontinuation beyond 90 days.

In this thesis chapter analysis, baseline depressive symptoms are only considered and there is no measurement of depressive symptoms at the point of insulin-requiring status or insulin initiation. However, research indicates depressive symptoms are persistent over time in people with type 2 diabetes (De Groot et al., 2010). Therefore, people with depressive symptoms at type 2 diagnosis are likely to have depressive symptoms upon insulin initiation as a result depressive symptoms should be considered when supporting people with type 2 diabetes initiating insulin.

4.5.5. Implications and future research

Depressive symptoms were the only psychological factor that was associated with shorter time to insulin initiation. Younger age and higher HbA1c predicted shorter time to insulin-requiring status and insulin initiation. These, therefore, are 2 good reasons to intervene early with insulin to prevent unnecessary damage from hyperglycemia especially for younger people who will live with type 2 diabetes for a long-time, increasing the risk of diabetes complications within their lifetime.

This thesis study, an 8-year follow-up of the SOUL-D cohort, may help to inform future research looking into whether psychological interventions that target depressive symptoms are effective in improving insulin self-management and glycemic control. Other research should consider whether those who started insulin continued with the therapy, to determine persistence and discontinuation. For people who discontinue insulin therapy, it would be interesting to examine the reasons why, for example, had their glycemic control improved or worsening psychological functioning. Participants from the SOUL-D cohort could be seen for further data collection to determine whether depressive symptoms, diabetes distress, or negative insulin beliefs reduce after insulin initiation by re-administering these psychological measures.

4.6. Chapter summary

This chapter reports on study 3 of this thesis which demonstrated that depressive symptoms were associated with insulin initiation. Depressive symptoms are potentially modifiable using treatments such as psychological interventions. The next 2 chapters, chapter 5 and chapter 6 report on the development of the DIME intervention. Based on findings from this chapter, the DIME intervention incorporates techniques to support people with depressive symptoms who may have difficulties managing their thoughts and behaviour towards insulin self-management.

Chapter 5 *: Developing DIME using the Behaviour Change Wheel*

5.1. Chapter scope

This chapter describes part of study 4 of this thesis in developing the DIME intervention. In this chapter, previous research (chapter 1) and thesis studies 1-3 (chapters 2-4), outlined in table 5.1, inform the behaviour change wheel to identify relevant behaviour change techniques for the DIME intervention. The DIME intervention was designed to build on the content from an existing insulin start group in south London (described in chapter 3).

Table 5.1- *Relevance of previous thesis chapters in the development of DIME*

Thesis chapter	**Relevance to DIME development**
Chapter 1: Thesis introduction.	Outlines problems associated with insulin treatment in type 2 diabetes.
Chapter 2: A systematic review and meta-analysis of psychological interventions to improve HbA1c in type 2 diabetes.	Outlines the types of psychological techniques and behaviour change technique categories which are effective in improving HbA1c in type 2 diabetes.
Chapter 3: Perspectives of group insulin education for people with type 2 diabetes.	Outlines the want and need for group insulin self-management education for those initiating insulin, in addition, the need for psychological support to address fears and concerns around insulin.
Chapter 4: Prospective study of the association between psychological status at type 2 diabetes diagnosis and insulin initiation.	Found an association between depressive symptoms and insulin initiation, demonstrating a need to provide additional support for people with depressive symptoms starting insulin therapy.

5.2. Introduction

The Behaviour Change Wheel is an integrated framework of 19 behaviour change frameworks (figure 5.1). The COM-B model (described in chapter 2) is the centre of the Behaviour Change Wheel and suggests that capability, opportunity, and motivation can influence behaviour (Michie et al., 2011). The middle and outer rings of the Behaviour Change Wheel represent intervention functions and policy categories respectively (figure 5.1) which link to the COM-B model. There are 9 intervention functions: training, education, environmental restructuring, enablement, modelling, persuasion, incentivisation, coercion, and restriction. Definitions of the intervention functions are provided in appendix 5.1. There are 7 policy categories which are defined in appendix 5.2: communication/marketing, guidelines, fiscal measures, regulation, legislation, environmental/social planning, service provision.

Identifying the components of the Behaviour Change Wheel in the context of a target behaviour(s), results in an intervention strategy outlining specific behaviour change techniques through which an intervention can be implemented. Behaviour change techniques can form the foundation of intervention design. The behaviour change wheel has been used in type 2 diabetes research to design interventions. For example, a self-management intervention for UK African and Caribbean communities with type 2 diabetes

(Moore, Rivas, Stanton-Fay, Harding, & Goff, 2019), and a complex intervention to improve medication intensification in type 2 diabetes for general practitioners (Murphy et al., 2017). One of these studies has planned feasibility work (Moore et al., 2019), the other study has a published protocol of proposed feasibility testing (Murphy et al., 2018). Another study used the behaviour change wheel to design a group intervention to prevent an infectious disease (melioidosis) in people with type 2 diabetes (Suntornsut et al., 2016). This study was tested for feasibility on 70 people with type 2 diabetes (non-randomised) (Suntornsut et al., 2018). Follow-up observations, questionnaires and one-to-one interviews found the behaviour to prevent the infection improved, in addition, the intervention was acceptable to participants.

The behaviour change wheel has not yet been utilised to design a psychological intervention to optimise insulin initiation in type 2 diabetes. The aim of study 4 of this thesis was to develop a nurse-led group psychological intervention (DIME) to optimise insulin initiation for people with type 2 diabetes.

5.3. Behaviour Change Wheel in DIME development

The three stages of the Behaviour Change Wheel to designing interventions are: 1) understanding the target behaviour; 2) identifying intervention functions; and 3) identifying content and implementation options. Each stage is built on several steps, figure 5.2. These stages are outlined in the remainder of this chapter.

5.3.1 Stage 1: Understand the behaviour

Stage 1 involved understanding the behaviour which was to be intervened. This was achieved through 4 steps: define the problem in behavioural terms; select target behaviour; specify the target behaviour; and identify what needs to change.

5.3.1.1. Define the problem in behavioural terms

The first step of intervention design was to define the problem in behavioural terms which involved specifying the precise population and behaviour of interest.

The target behaviour for the DIME intervention group was ‘improving insulin self-management’ for people with type 2 diabetes. This behaviour generally occurs within primary care, general practitioners and community diabetes specialist nurses are usually involved in supporting people with type 2 diabetes to use and manage insulin.

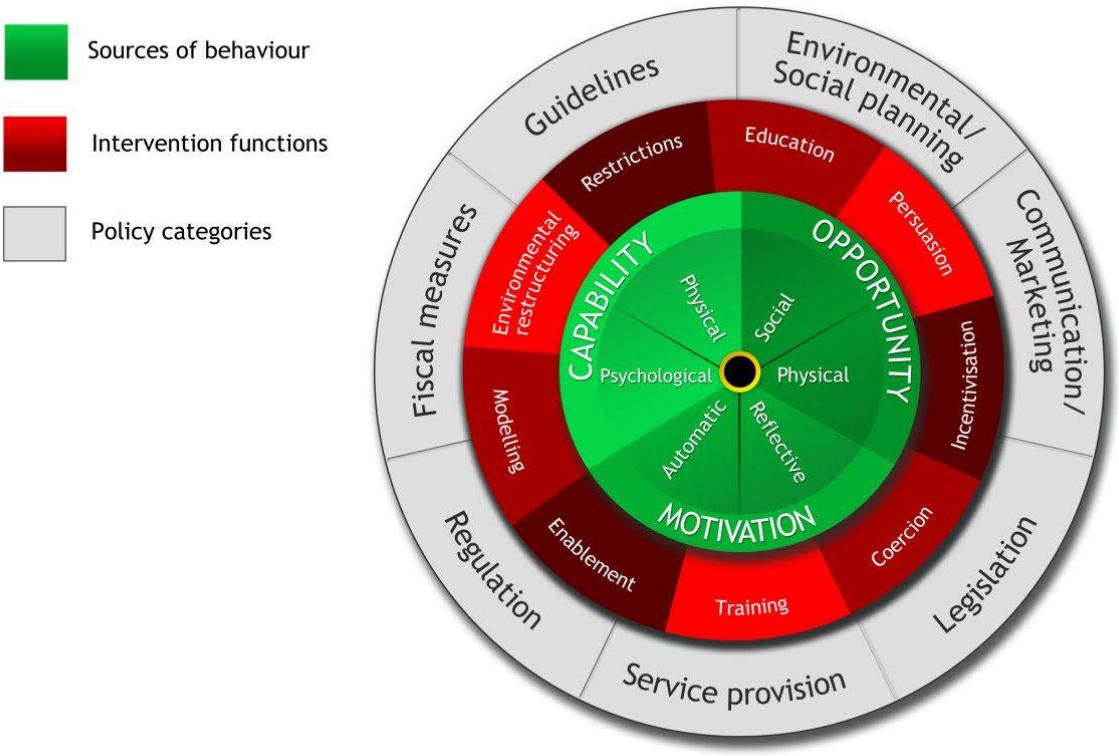

Figure 5.1- *The behaviour change wheel (Michie, van Stralen, & West, 2011)*

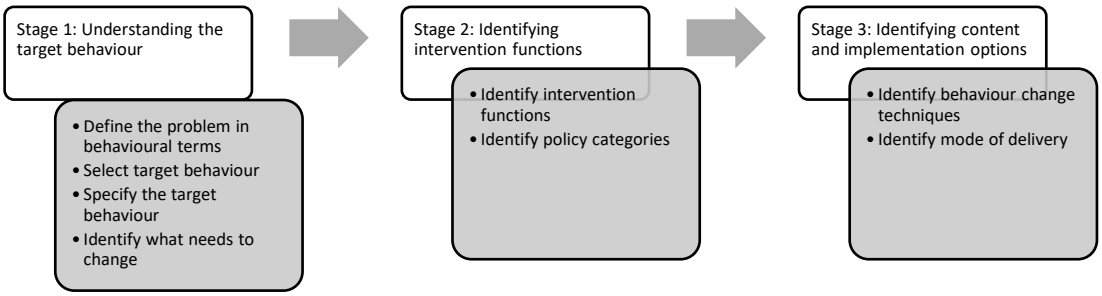

Figure 5.2- *Stages of the Behaviour Change Wheel*

5.3.1.2. Select target behaviour

Improving insulin self-management encompasses several behaviours. To help select a more specific target behaviour, a list of potential behaviours was generated:

- Injecting insulin
- Treatment of hypoglycaemia
- Insulin dose titration
- Storing and travelling with insulin
- Blood glucose checking
- Physical activity
- Carbohydrate awareness

The next step in this stage of the Behaviour Change Wheel was to prioritise the behaviours and evaluate them based on how promising they were in the following domains: impact of behaviour change; the likelihood of changing the behaviour; the likelihood of the behaviour impacting other behaviours (spill over effect); and how easy it is to measure the behaviour.

'Less is more' is often relevant in intervention design, to concentrate on a few behaviours in-depth rather than spend less time intervening several behaviours. However, it is important to consider that target behaviours are often surrounded by multiple other behaviours (Presseau, Tait, Johnston, Francis, & Sniehotta, 2013). Owing to the nature of insulin education, it is essential to intervene towards all the above listed behaviours to ensure the safe delivery of insulin therapy to best avoid hypoglycaemia and hyperglycaemia. Behaviours which are not addressed in current insulin start group in south London include physical activity and diet (i.e. carbohydrate awareness) relating to insulin self-management. These were expressed as important to insulin education by participants who took part in interviews in chapter 3 (study 2). 'Improving insulin self-management' was agreed as a target behaviour, as previously stated, which encompasses all the above behaviours.

5.3.1.3. Specify the target behaviour

The focus now was to specify the target behaviour (table 5.2). Similarly, David French and colleagues suggest the initial mechanisms of an intervention can be defined by outlining: "who needs to do what differently, when, where, how?" (French et al., 2012).

In the previous step, the target behaviour was identified: improving insulin self-management. Diabetes specialist nurses need to deliver the intervention owing to their

specialist knowledge in diabetes and insulin, diabetes specialist nurses also currently deliver the current insulin start groups in south London (who). The DIME intervention

Table 5.2-*Specifying the target behaviour for DIME intervention*

Describe the target behaviour according to who needs to do what, when, how often and with whom	
Target behaviour:	Improving insulin self-management
Who needs to perform the behaviour?	Diabetes specialist nurses
What do they need to do differently to achieve the desired change?	Group insulin education underpinned by psychological techniques
When do they need to do it?	Within 1 month of insulin prescription
Where do they need to do it?	Local venue (general practice, hospital, community venue)
How often do they need to do it?	3 sessions
With whom do they need to do it?	people with type 2 diabetes

needs to differ from the current insulin start group in south London by offering additional psychological support to address concerns around insulin therapy (what). The behaviour needs to be targeted within 1 month of insulin prescription (when). Interviews from chapter 3 revealed some people with type 2 diabetes were negatively affected by the varying knowledge base of the group in relation to insulin, if people enter the group around the same time i.e. all new to insulin, then this aims to reduce this negative view. However, psychological training to best manage group dynamics should also address this problem. The intervention should be delivered at a convenient location for the people with type 2 diabetes to access, this should be their local general practice, hospital, or local community venue within the borough (where). The current insulin start group is 2 sessions, and DIME was designed with 3 sessions to allow the addition of relevant educational content and adopting psychological delivery techniques (how often). The intervention is for people with type 2 diabetes new to insulin injection therapy (with whom).

5.3.1.4. Identify what needs to change

Evidence from chapters 1-4 informed what needed to change, and which COM-B components were relevant, outlined in table 5.3. Chapter 1 (introduction chapter) relayed the psychological problems associated with insulin initiation and continued self-management including psychological insulin resistance, and how treatment beliefs or treatment burden are associated with insulin adherence or persistence. Aspects of the COM-B model could change to address these psychological problems. For example, increasing knowledge and skill (psychological and physical capability) around administering

insulin and its regimen, insulin efficacy, and side effects including hypoglycaemia (how to prevent and treat) and weight gain, could help alleviate emotional (e.g. fears) and cognitive (e.g. misconceptions) psychological insulin resistance as well as reduce treatment burden or negative insulin beliefs to promote insulin adherence and persistence. The opportunity for social interaction (social opportunity) in a group setting would allow for shared social norms and could help address social psychological insulin resistance. Chapter 1 also provided evidence from previous literature supporting the need for knowing how to inject (capability) (Polonsky et al., 2019), overcoming psychological insulin resistance (capability) (Ng et al., 2015), remembering to inject (capability) (Brod, Pohlman, et al., 2014), self-monitoring blood glucose (capability) (Jenkins et al., 2010), action plans (capability) (Dellasega et al., 2012), social support (opportunity) (Bogatean & Hâncu, 2004a), and HbA1c related to reducing complications (motivation) (Jenkins et al., 2010). Chapter 2 (study 1) found the most frequently used behaviour change categories associated with improvement in glycaemic control were 'social support'(opportunity), 'goals and planning' (capability; motivation), and 'feedback and monitoring' (capability). In chapter 3 (study 2) themes generated in the qualitative analysis were linked to COM-B components, for example, 'Ongoing self-management success (theme 3.1) links to capability; 'Need for more peer support' (theme 3.2) links to opportunity, and 'insulin concerns post-group' (theme 3.3) links to motivation. Chapter 4 (study 3) provided evidence that depressive symptoms are associated with insulin initiation (motivation). On review of all this evidence, all COM-B domains were identified as needing to change (capability, opportunity, and motivation) for insulin self-management to improve.

5.3.2. Stage 2: Identify intervention functions

A 'behavioural diagnosis' at stage 1 identified what needs to change (all COM-B domains) to improve insulin self-management. Stage 2 of the Behaviour Change Wheel involved linking the behavioural diagnosis with intervention functions, in addition to identifying which policy categories the intervention can be implemented through.

5.3.2.1. Identify intervention functions

The COM-B components link to the intervention functions shown in table 5.4 (Michie et al., 2014) and figure 5.1. Intervention functions are defined in appendix 5.1.

The next step was to determine which intervention functions were appropriate for intervention development as evaluated by the APEASE (Affordability, Practicability, Effectiveness and cost-effectiveness, Acceptability, Side effects and safety, Equity) criteria. Full definitions of the APEASE criteria are provided in appendix 5.3. The intervention

functions which met all APEASE criteria (table 5.5) and were identified for DIME development were: education (e.g. educating people with type 2 diabetes about diabetes and insulin self-management), persuasion (e.g. persuading people with type 2 diabetes that insulin therapy is the best treatment to improve HbA1c and prevent long term complications), training (e.g. training people with type 2 diabetes on how to inject insulin and to check blood glucose), environmental restructuring (e.g. relating to access to education group, for example, location and time of sessions), modelling (e.g. demonstrate how to use a needle), and enablement (e.g. goal setting and reviewing goals).

The three intervention functions which did not meet APEASE criteria were: incentivisation, coercion, and restriction. It was evaluated as not affordable to incentivise people to manage with insulin therapy, it was not acceptable to coerce people into using insulin therapy, and there was no option to 'restrict' in relation to insulin management (not practical).

Table 5.3- *Identifying what needs to change according to COM-B for DIME intervention*

COM-B component	**What needs to change relevant to domain?**	**Evidence for need to change**
Physical capability	Know how to inject insulin.	Chapter 1, 3
Psychological capability	Know more about insulin and why it is important.	Chapter 1& 3
	Overcome mental obstacles e.g. reduce unwanted feelings towards insulin such as fear of injections.	Chapter 1& 3
	Remembering to inject.	Chapter 1&3
	Self-monitoring blood glucose. Action plans for improving management with insulin.	Chapter 1, 2 &3
Physical opportunity	Insulin education accessibility. Have more time for injections. Making sure insulin is available when needed e.g. transporting insulin. Have triggers to prompt injection.	Chapter 3
Social opportunity	Social support from healthcare professionals, family, friends, and other people with diabetes to manage with insulin. Have more people around them injecting insulin.	Chapter 1, 2& 3
Reflective motivation	Explore cultural beliefs towards diabetes.	Chapter 3
	Having confidence to inject.	Chapter 3
	Believe that insulin will improve HbA1c/symptoms or prevent complications.	Chapter 1& 3
	Believe that insulin with reduce blood glucose and prevent complications.	Chapter 1& 3
	Explore intentions in continuing to self-manage with insulin therapy.	Chapter 3
	Goal setting in relation to managing with insulin therapy.	Chapter 2& 3
Automatic motivation	Understanding the benefits in continuing insulin therapy.	Chapter 3
	Reduce fears and negative emotions towards insulin therapy. Reduce depressive symptoms which may impact insulin self-management.	Chapter 3 & 4

Table 5.4- *How intervention functions link to COM-B*

COM-B	**Intervention functions**
Physical capability	Training
Psychological capability	Education, Environmental, Restructuring, Enablement, Training, Modelling
Physical opportunity	Training, Restriction, Environmental restructuring, Enablement
Social opportunity	Restriction, Environmental restructuring, Modelling, Enablement
Reflective motivation	Education, Persuasion, Modelling, Enablement, Incentivisation, Coercion
Automatic motivation	Training, Incentivisation, Coercion, Environmental restructuring
	Persuasion, Incentivisation, Coercion, Modelling, Enablement

Table 5.5- *APEASE assessment of intervention functions for DIME*

Intervention functions	**Does the intervention function meet the APEASE criteria in the context of improving uptake of continuing insulin therapy?**
Education	Yes
Persuasion	Yes
Incentivisation	No (Not affordable)
Coercion	No (Not acceptable)
Training	Yes
Restriction	No (Not practical)
Environmental restructuring	Yes
Modelling	Yes
Enablement	Yes
Selected intervention functions: Education, persuasion, training, restructuring, modelling, enablement	

5.3.2.2. Identify policy categories

The intervention functions, as described in the previous step, link to policy categories (table 5.6). The idea of the DIME intervention was to replace an existing insulin start group in south London, hence DIME lends itself towards the following policy categories: service provision; communication and marketing; environmental and social planning. The intervention is a service provision as it is delivering a service within primary care. The communication and marketing category refer to printed materials for people with type 2 diabetes to take home following the insulin group. The environmental and social planning category refers to the location the group is held for ease of access. This is important as evidence suggests the inconvenient location is a barrier to attending group-based type 2 diabetes education (Coates, Slevin, Carey, Slater, & Davies, 2018; Horigan, Davies, Findlay-White, Chaney, & Coates, 2017; McSharry, McGowan, Farmer, & French, 2016; Winkley et al., 2015; Winkley et al., 2018). According to APEASE criteria assessment, the other policy categories were either not practical, acceptable or affordable (table 5.6). Guidelines for what to include in insulin education for people starting insulin treatment already exist (NICE, 2017).

5.3.3. Stage 3: Identify content and implementation options

Stage 3 of the Behaviour Change Wheel involved identifying content and implementation options. This was achieved with 2 steps outlined below: identify behaviour change techniques; and identify the mode of delivery.

5.3.3.1. Identify behaviour change techniques

At this stage intervention functions and associated COM-B components were linked to most commonly used behaviour change techniques (Michie et al., 2014), table 5.7. These behaviour change techniques were evaluated using the APEASE criteria. Any additional relevant behaviour change techniques were also listed in table 5.7. Specific behaviour change technique examples relating to DIME are provided in the draft intervention strategy in table 5.9. Behaviour change techniques categories which were identified in the meta-analysis from chapter 2 of this thesis (study 1), 'social support', 'goals and planning' and 'feedback and monitoring', were also included in the additional relevant behaviour change technique column of table 5.7 if not already stated. The behaviour change technique 'Social support (unspecified)' includes both motivational interviewing and cognitive behavioural therapy, of which both techniques were also used in the development of DIME (see chapter 6 for more information). Examples of additional relevant behaviour change techniques which correspond with the 'feedback and monitoring' category include: 'biofeedback' and

'self-monitoring of outcome of behaviour'. There were no additional relevant behaviour change techniques which correspond with the 'goals and planning' category as these were already included in the 'most commonly used behaviour change techniques' column including: 'goal setting (behaviour)', 'goal setting (outcome)', 'problem-solving', 'action planning', 'review behaviour goals', and 'review outcome goals'.

Table 5.6- *Identifying policy categories for DIME*

Intervention function	**Policy categories**	**Does the policy category meet the APEASE criteria?**
Education	Communication/marketing	Yes
	Guidelines	Guidelines already exist for initiating insulin therapy
	Regulation	Not practical
	Legislation	Not acceptable
	Service provision	Yes
Persuasion	Communication/marketing	Yes
	Guidelines	Guidelines already exist for initiating insulin therapy
	Regulation	Not practical
	Legislation	Not acceptable
	Service provision	Yes
Training	Guidelines	Guidelines already exist for initiating insulin therapy
	Fiscal measures	Not affordable
	Regulation	Not practical
	Legislation	Not acceptable
	Service provision	Yes
Restructuring	Guidelines	Guidelines already exist for initiating insulin therapy
	Fiscal measures	Not affordable
	Regulation	Not practical
	Legislation	Not acceptable
	Environmental/social planning	Yes (in context of accessibility to education)
Modelling	Communication/marketing	Yes
	Service provision	Yes
Enablement	Guidelines	Guidelines already exist for initiating insulin therapy
	Fiscal measures	Not affordable
	Regulation	Not practical
	Legislation	Not acceptable
	Environmental/social planning	Yes
	Service provision	Yes
Policy categories selected: Communication/marketing; service provision; environmental/social planning		

Table 5.7- *Identifying behaviour change techniques for DIME*

Intervention function	COM-B component	Most commonly used behaviour change techniques	Does the behaviour change technique meet the APEASE criteria?	Additional relevant behaviour change techniques
Education	Psychological capability	Information about social and environmental consequences	Not relevant in this context	• Biofeedback • Self-monitoring of outcome of behaviour • Information about emotional consequences • Information about others' approval
		Information about health consequences	Yes	
	Reflective motivation	Feedback on behaviour	Yes	
		Feedback on outcome(s) of the behaviour	Yes	
		Prompts/cues	Yes	
		Self-monitoring of behaviour	Yes	
Persuasion	Reflective motivation	Credible source	Yes	• Biofeedback • Focus on past success • Verbal persuasion about capability • Information about emotional consequences • Information about others' approval • Social comparison
		Information about social and environmental consequences	Not relevant in this context	
	Automatic motivation	Information about health consequences	Yes	
		Feedback on behaviour	Yes	
		Feedback on outcome(s) of the behaviour	Yes	
Training	Physical capability	Demonstration of the behaviour	Yes	• Biofeedback • Self-monitoring of outcomes of behaviour • Habit formation
		Instruction on how to perform a behaviour	Yes	
	Psychological capability	Feedback on the behaviour	Yes	
		Feedback on the outcome(s) of the behaviour	Yes	
		Self-monitoring of behaviour	Yes	
		Behavioural/practical rehearsal	Yes	

	Automatic motivation		
Restructuring	Physical opportunity	Adding objects to environment	Not relevant in this context
		Prompts/cues	Yes
		Restructuring physical environment	Yes
Modelling	Social opportunity	Demonstration of the behaviour	Yes
	Psychological capability		
	Reflective motivation		
	Automatic motivation		
Enablement	Psychological capability	Social support (unspecified)	Yes
		Social support (practical)	Yes
	Reflective motivation	Goal setting (behaviour)	Yes
		Goal setting (outcome)	Yes
		Adding objects to the environment	Not relevant in this context
	Automatic motivation	Problem solving	Yes
		Action planning	Yes

Self-monitoring of the behaviour	Yes
Restructuring the physical environment	Not relevant in this context
Review behaviour goals	Yes
Review outcome goals	Yes

5.3.3.2. Identify mode of delivery

There are two main modes of delivery: face-to-face, and distance which are categorised further in table 5.8. The three modes of delivery which met APEASE criteria were: face-to-face (group), print media (leaflet), and phone (phone helpline). At least 3 telephone follow-up calls would be delivered over DIME duration to check on progress as this is the current level of care for people with type 2 diabetes starting insulin. Individual face-to-face was rated as not cost-effective. Modes of delivery which were rated as not affordable were broadcast media, outdoor media, newspaper, digital media, and individually accessed computer programme. Mobile phone text was rated as not practical and not safe. Telephone calls were evaluated as more appropriate to check in on people with type 2 diabetes starting insulin and answer any queries or concerns. Individually accessed computer programmes were rated as not practical.

5.4. Behaviour Change Wheel draft DIME intervention strategy

Table 5.9 outlines a draft DIME intervention strategy based on all the components of the Behaviour Change Wheel (relevant intervention functions, policy categories, COM-B components). Twenty-seven behaviour change techniques were identified to deliver the DIME intervention, examples are included in table 5.9.

Table 5.8- *Identifying mode of delivery for DIME*

Mode of delivery				**Does mode of delivery meet the APEASE criteria?**
Face-to-face	Individual			Not cost-effective
	Group			Yes
Distance	Population-level	Broadcast media	TV	Not affordable
			Radio	Not affordable
		Outdoor media	Billboard	Not affordable
			Poster	Not affordable
		Print media	Newspaper	Not affordable
			Leaflet	Yes
		Digital media	Internet	Not affordable
			Mobile phone app	Not affordable
	Individual level	Phone	Phone helpline	Yes
			Mobile phone text	Not practical, potential safety concerns
		Individually accessed computer programme		Not affordable or practical

Table 5.9- *Draft DIME intervention strategy based on behaviour change wheel*

Policy categories	**Intervention function**	**COM-B**	**Behaviour change techniques [BCTTv1 code]**	**Intervention strategy – examples within context**
Communication/marketing • Educational materials to support group. Service provision • Service to be provided in primary care. Environmental/social planning • Accessibility to education.	Education • Around insulin and associated self-management behaviours. Persuasion • Persuading that insulin injections lead to positive consequences. Training • On injecting insulin and self-monitoring of blood glucose. Restructuring • Time and location of group for easy access Modelling • Modelling insulin injection behaviour Enablement • Reducing barriers to insulin injections, and increase	Psychological capability • Know more about insulin and why it is important • Overcome mental obstacles e.g. reduce unwanted feelings towards insulin such as fear of injections Physical capability • Know more about how to deliver insulin Physical opportunity • Access to insulin education Social opportunity • Have more people around them doing it • Have social support from others Reflective motivation • Believe it would be a good thing to do • Develop better plans for doing it • Develop routines and habit of doing it Automatic motivation • Feel you want to do it enough • Feel you need to do it enough	1. Goal setting (behaviour) [1.1] 2. Problem solving [1.2] 3. Goal setting (outcome) [1.3] 4. Action planning [1.4] 5. Review of behaviour goal(s) [1.5] 6. Review of outcome goal(s) [1.7] 7. Feedback on the behaviour [2.2] 8. Self-monitoring of behaviour [2.3] 9. Self-monitoring of outcome of behaviour [2.4] 10. Biofeedback [2.6] 11. Feedback on outcome(s) of the behaviour [2.7]	1. Set goal of checking blood glucose every morning and taking insulin every day. 2. Prompt group to identify barriers to insulin treatment and discuss strategies for overcoming them. 3. Set morning blood glucose goal as an outcome for titrating insulin to correct dose. 4. Encourage a plan to carry hypo treatment when going out. Encourage a plan to inject insulin in same context every day. 5. Review behaviour goals of previous sessions and address any issues, adjust accordingly. 6. Examine how much morning blood glucose readings have reduced and encourage titration of insulin dose accordingly (e.g. need more or less insulin to achieve outcome). 7. Provide feedback on performance of injecting insulin. 8. Ask group to record daily insulin doses. 9. Ask group to record their daily morning blood glucose readings. 10. Inform the person of their HbA1c reading to improve adoption of insulin injections. 11. Inform the person of their reduction in blood glucose readings following starting insulin therapy. 12. Motivational interviewing and cognitive behavioural therapy. 13. If group brings someone along with them to group, ask them to help remind people with type 2 diabetes to take insulin or check blood glucose.

	capability or opportunity		12. Social support (unspecified) [3.1] 13. Social support (practical) [3.2] 14. Instruction on how to perform a behaviour [4.1] 15. Information about health consequences [5.1] 16. Salience of consequences [5.2] 17. Information about emotional consequences [5.6] 18. Demonstration of the behaviour [6.1] 19. Social comparison [6.2] 20. Information about others' approval [6.3] 21. Prompts/cues [7.1] 22. Behavioural practice/ rehearsal [8.1] 23. Habit formation [8.3] 24. Credible source [9.1]	14. Advise the group how to inject insulin or check blood glucose correctly. 15. Explain how injecting insulin can improve HbA1c and prevent diabetes complications. 16. Produce pictures of a fatty liver to highlight dangers of being overweight/obese. 17. Explain that injecting insulin to reduce blood glucose can improve wellbeing. 18. Diabetes specialist nurses and other group members demonstrates taking insulin injection and blood glucose checking. 19. Compare confidence or importance of taking insulin amongst group. 20. Discuss with group how family/friends will approve of insulin injections to improve health. 21. Introduce to group prompts/cues for remembering to take insulin e.g. phone alarm. 22. Prompt group to practice insulin injection technique using water pen and sponge in session. 23. Prompt group to take their insulin in the same context (e.g. room/time) everyday (if possible). Discuss and compare personal strategies (e.g. after brushing teeth) 24. The group is delivered by a diabetes specialist nurse who will emphasise the importance of insulin injection therapy. 25. Arrange location and time of the group so it is accessible to people attending. 26. Tell the group they can successfully reduce HbA1c using insulin despite recent unwanted glucose readings/hba1c OR they can successfully inject insulin (or check blood glucose) despite recent relapse in behaviour.

	25. Restructuring physical environment [12.1] 26. Verbal persuasion about capability [15.1] 27. Focus on past success [15.3]	27. Advise to describe successes in injecting insulin and checking blood glucose.

5.5. Discussion

Here, the behaviour change wheel has been applied to designing the DIME intervention, a psychological intervention to support insulin initiation for people with type 2 diabetes. Stage 1 of the behaviour change wheel provided a behavioural diagnosis, i.e. 'improving insulin self-management', where specific target behaviours included: injecting insulin, treating hypoglycaemia, insulin dose titration, storing and travelling with insulin, blood glucose checking, physical activity, and carbohydrate awareness. DIME is a psychologically informed diabetes specialist nurse-led group 3-session intervention for people with type 2 diabetes within one month of insulin prescription at a local health or community location. Evidence from previous studies of this thesis (1-3) identified all domains of the COM-B model (capability, opportunity, and motivation) were required to improve insulin self-management. Stage 2 of the behaviour change wheel identified intervention functions and policy categories relevant to the COM-B components which were evaluated using the APEASE criteria. The intervention functions relevant to DIME included; education, persuasion, training, environmental restructuring, modelling and enablement. The policy categories evaluated as relevant to DIME included service provision; communication and marketing; environmental and social planning. Stage 3 identified the mode of delivery for DIME, 3 of which met APEASE criteria: face-to-face (group), print media (leaflet), and phone (phone helpline). Stage 3 also identified specific behaviour change techniques linked to previously outlined intervention functions and associated COM-B domains. Twenty-seven behaviour change techniques were evaluated as relevant to DIME. This encompassed the following behaviour change technique categories: 'goals and planning', 'feedback and monitoring', 'social support', 'shaping knowledge', 'natural consequences', 'comparison of behaviour', 'associations', 'repetition and substitution', 'comparison of outcomes', 'antecedents', and 'self-belief'.

5.5.1. Behaviour change wheel limitations

A potential limitation is there are too many target behaviours which surround 'improving insulin self-management', this makes it difficult to disentangle which elements of the intervention might be effective i.e. 'the active ingredients'. Several behaviours must be targeted to ensure safe delivery of insulin, in addition to providing a rounded education which people with type 2 diabetes desire.

A limitation of the intervention design at this stage is the assessment of APEASE criteria. The criteria were discussed only between two researchers (RU & KW). To make a valid 'acceptability' assessment, judgement from patient public involvement (PPI) may have

been beneficial. However, the best judgements were made based on research (RU & KW) and clinical (KW) experience. Following pilot (chapter 7) and feasibility testing (beyond PhD thesis), further funding could incorporate PPI to strengthen intervention design.

5.6. Chapter summary

Through using a current integrated framework, the Behaviour Change Wheel, 27 behaviour change techniques were identified as the basis for the DIME educational content, materials, and activities. The following chapter (chapter 6) provides an in-depth description of DIME outlining specific intervention content, format and structure.

Chapter 6 : *DIME intervention description*

6.1. Chapter scope

This chapter describes study 4 of this thesis and provides the core information regarding the DIME intervention. It is reported according to the items of the Template for Intervention Description and Replication (TIDieR) checklist (appendix 6.1), namely the 'why', 'what', 'who', 'how', 'where' and 'when' of the intervention. Chapter 5 used the Behaviour Change Wheel to identify relevant behaviour change techniques for DIME. However, the behaviour change wheel does not detail how to develop specific content for sessions, psychological techniques, or intervention materials. Therefore, this chapter discusses the additional rationale and theory underpinning DIME.

6.2. Intervention brief name

The intervention is called **DI**abetes self-**M**anagement **E**ducation (DIME).

6.3. Why? Rationale and theory

6.3.1. Diabetes education guidelines

In the UK, diabetes self-management education can be categorised into three levels: level one (information and one-to-one support); level two (informal learning such as peer support); and level three (structured education). For diabetes education to be defined as level 3 structured education, it must meet national criteria including being evidence-based, theory-driven, involving supporting materials, curriculum written-down, delivered by appropriately trained educators, quality assured and is audited (NICE, 2011; SIGN, 2017). The current insulin start group in south London is not a structured education programme. In addition, feedback from people with type 2 diabetes who have attended the insulin start group (chapter 3, study 2) suggests the current level of education is not supportive enough to address fears and concerns around insulin therapy. A 2018 consensus report by ADA and EASD for management of hyperglycaemia in type 2 diabetes expands on these UK definitions and recommends standards for key components of diabetes self-management education and support (DSMES). These guidelines similarly outline the need for evidence-based theory-driven curriculum, delivered by trained quality-assured professionals, that is quality audited (Davies et al., 2018). In addition, the ADA/EASD standards suggest DSMES is individualised to meet needs of the person(s) (e.g. language and culture), delivered to group or individual, includes content on psychological issues and concerns, available at critical times (e.g. when transitions in treatment occur), monitors progress in health status and quality of life. The DIME intervention aims to become a structured education programme and meet these NICE/SIGN and ADA/EASD standards. In the scope of this thesis, DIME development aims to incorporate evidence-based theory-driven curriculum delivered by a trained (in motivational interviewing) diabetes specialist nurse, delivered to

a group, includes content on psychological issues and concerns, available at insulin initiation (i.e. a critical time), and monitors progress, for example, insulin dosage and blood glucose readings.

NICE guidelines recommend a structured education programme when starting insulin therapy with the following curriculum (NICE, 2015):

- Injection technique
- Injection sites
- Telephone support
- Self-monitoring
- Insulin dose titration
- Dietary awareness
- Driving guidance (i.e. DVLA regulations)
- Hypoglycaemia
- Support from trained healthcare professional

The DIME curriculum includes all these NCIE guideline recommendations for insulin education.

6.3.2. Psychological techniques

The theory of planned behaviour (Ajzen, 1991) is a health psychology model comprised of three components (subjective norms; attitudes; and perceived behavioural control) which all predict intention to perform a behaviour. Intentions to perform a behaviour predict engaging in a behaviour. Motivational interviewing techniques can influence and explore attitudes (e.g. towards insulin injections), perceived behavioural control (e.g. self-efficacy towards carrying out insulin injections) and intentions (e.g. towards delivering insulin therapy) as well as encouraging maintenance of the behaviours. A major criticism of the theory of planned behaviour is there is a gap between intentions and performing a behaviour known as the intention-behaviour gap (Sheeran, 2002). However, cognitive behavioural therapy techniques can be used to bridge this gap (Hobbis & Sutton, 2005), with specific examples provided in section 6.4.1.2. of this chapter. Therefore, motivational interviewing and cognitive behavioural therapy techniques were relevant to DIME intervention development. In support of this, a meta-analysis of psychological interventions for people with type 2 diabetes (study 1, chapter 2) revealed counselling (mainly motivational interviewing) and cognitive behavioural therapy techniques were effective in reducing HbA1c. No studies included in the meta-analysis used motivational interviewing or cognitive behavioural therapy techniques in the context of group insulin education for insulin initiation or insulin self-management for people with type 2 diabetes. Hence, DIME

is novel in exploring these techniques in relation to insulin treatment for people with type 2 diabetes.

Social cognitive theory (Bandura, 1991) is a theoretical concept which relates to the 'subjective norms' component of the theory of planned behaviour referring to the importance of social support in influencing behaviour. A systematic review revealed increased social support increases positive outcomes in type 2 diabetes (Strom & Egede, 2012), which is relevant to the DIME intervention being group-based. The aim of DIME being a group intervention is to provide social support to reduce social psychological insulin resistance i.e. social stigma and lack of social support. In addition, social support was one of the most frequently used behaviour change technique categories in chapter 2 (study 1) meta-analysis. The behaviour change technique 'social support (unspecified)' encompasses motivational interviewing and cognitive behavioural therapy techniques. Therefore, strengthening the evidence for underpinning DIME with motivational interviewing and cognitive behavioural therapy techniques.

6.3.2.1. Motivational interviewing

A description of motivational interviewing is provided in chapter 1 of this thesis. There are four cornerstones, four processes and four foundational practice skills of motivational interviewing.

The cornerstones of motivational interviewing are partnership; acceptance; compassion; and evocation. **Partnership** refers to the collaboration between a healthcare professional and patient, for example, the person with type 2 diabetes is seen as the diabetes expert and should be involved with decision making. **Acceptance** is where the healthcare professional accepts the person as they are e.g. the person with type 2 diabetes should have autonomy and be affirmed for their attempts to change health behaviours (not criticised for what they have not done). **Compassion** relates to having a person's best interest at the forefront. **Evocation** acts on calling on the motivation that already exists rather than installing it.

The processes of motivational interviewing include **engaging** (e.g. understanding the point of view of the person with type 2 diabetes); **focusing** (making a clear goal for health behaviour change); **evoking** (e.g. evokes the person's own motivation and knowledge about change); **planning** (e.g. collaboration between a healthcare professional and the person with type 2 diabetes to identify next steps to take). The righting reflex refers to a healthcare professional correcting a patient or telling a patient what they should be doing,

this must be avoided in motivational interviewing to allow evoking of a person's own motivation which best serves behaviour change.

The foundational practise skills of motivational interviewing (OARS) to be conducted by a healthcare professional include: **open questions** (as opposed to closed questions which elicit one-word answers); **affirmations** (positively commenting on successes and efforts to change or work towards a goal); **reflections** (statements which aim to mirror what the person with type 2 diabetes has said to check understanding and perspective); and **summarising** (combines several reflections to give the person with type 2 diabetes an overview of what has been said).

The DIME intervention uses group motivational interviewing which draws on the same cornerstones, processes and foundational practice skills as individual motivational interviewing. In addition, motivational interviewing in groups should promote positive interactions among group members, balance group dynamics, and include two or more group members with one or more group facilitators who meet face-to-face (Wagner & Ingersoll, 2012).

6.3.2.2. Cognitive behavioural therapy

Cognitive behavioural therapy is defined in chapter 1 of this thesis. Cognitive behavioural therapy was initially developed to treat depression (Beck & Alford, 2009), because of how cognitions (thoughts, attitudes) can influence behaviour. Cognitive behavioural therapy assumes that if someone has depressive symptoms, they may have unrealistic thought patterns which can negatively influence engaging in positive health behaviours (Beck, 1970). As previously outlined common maladaptive cognitions (not limited to people with depression) which aim to be addressed in cognitive behavioural therapy include:

- Personalising (negatively attributing outcomes to oneself)
- Catastrophising (thinking the 'worst-case scenario')
- All or nothing (holding high standards, might not engage in behaviour change unless success is certain).

Relating to type 2 diabetes and insulin, people with type 2 diabetes may intend to check their blood glucose, however, they may attribute negative blood glucose readings to be their fault (personalising) which could disengage them from the behaviour. Cognitive behavioural therapy techniques would be useful here to challenge these types of unhelpful thinking styles to help people with type 2 diabetes understand that there are factors which fall outside an individual's control contributing to changes in blood glucose. This would help

people with type 2 diabetes engage in the behaviour of blood glucose checking with a more positive perspective.

The findings of study 3 in chapter 4 found that depressive symptoms are associated with shorter time to insulin requirement and initiation. Therefore, cognitive behavioural therapy techniques are highly relevant to incorporate in the development of DIME to address depressive symptoms.

6.3.2.3. Psychological techniques and diabetes education

The MOtiVational interviewing InTervention (MOVE-IT) is an education manual which integrates motivational interviewing and cognitive behavioural therapy techniques to encourage weight loss and physical activity to reduce the cardiovascular risk for those at high risk (Bayley et al., 2015). Another intervention is known as the Diabetes-6 (D-6) study, trained nurses in 6 skills taken from motivational interviewing and cognitive behavioural therapy to help improve HbA1c for people with type 2 diabetes (Ismail et al., 2018). The six skills included: active listening, managing resistance, directing change, supporting self-efficacy, addressing health beliefs, and shaping behaviours. Both MOVE-IT and D-6 manuals were useful in the development of DIME owing to the in-depth description of psychological techniques and how to deliver them. In addition, activities were adapted to be relevant towards insulin (discussed in section 6.4.1. of this chapter).

6.3.2.4. The stages of change

The transtheoretical model was initially developed by Prochaska & colleagues (Prochaska & Velicer, 1997) to identify stages of change required to successfully quit smoking. The transtheoretical model has more recently been studied on a range of applications including depression (Acton, Prochaska, Kaplan, Small, & Hall, 2001) and other health behaviours such as medication adherence (Willey et al., 2000), increasing physical activity (Titze, Martin, Seiler, Stronegger, & Marti, 2001) and weight loss (Mastellos, Gunn, Felix, Car, & Majeed, 2014). The transtheoretical model has not been specifically applied to insulin self-management. The stages of change include **pre-contemplation** (do not feel there is a problem and do not feel the need to make changes, even if other people do), **contemplation** (ready to change and can see the benefits of engaging in a new behaviour), **preparation** (planning to engage in a new habit), **action** (engaging in the new behaviour), **maintenance** (the new behaviour is becoming a habit), and **relapse** (the new behaviour has stopped or there are periods of stopping and re-starting). There is evidence for integrating motivational interviewing with the stages of change whereby motivational interviewing techniques give the group a chance to reflect on reasons for change and personal values

(Wagner & Ingersoll, 2012). The stages of change were applied to insulin injections and included in the DIME (see 6.4.1.3 for more detail). The aim of using this theory is to not only recognise the current state of mind i.e. readiness to initiate insulin within the DIME intervention but in future insulin self-management to help overcome periods of psychological insulin resistance which lead to nonadherence or non-persistence (i.e. overcoming relapse).

6.3.3.5. The behaviour change wheel

The theory of planned behaviour on its own does not consider behaviour maintenance, habit, or emotional processing (West & Brown, 2013). The behaviour change wheel is a more recent behaviour change framework which takes in consideration internal (psychological and physical) and external (environmental) changes (Michie et al., 2011) to aid the design of behavioural interventions. DIME was developed using the behaviour change wheel which results in appropriate and relevant behaviour change techniques described in detail in chapter 5 and section 6.4.2.2 of this chapter.

6.3.3. Dietary content

The dietary content in DIME shares principles common to other insulin education programmes such as CLIMB (Carbohydrate Lifestyle Insulin Management and Beyond; CLIMB) (Addington & Holcombe, 2017) and X-PERT (Deakin, 2015). All include sessions on carbohydrate awareness (i.e. what carbohydrates are and foods containing them), carbohydrate counting (how many carbohydrates are in certain foods), glycaemic index, and weight and insulin. Dietary content which is not included in these programmes that is incorporated into DIME is 'time-restricted eating'. Time-restricted eating refers to eating all foods in the day but in a shorter time frame e.g. within 6-12 hours instead of the normal 12-15. There is evidence for this leading to weight loss which reduces insulin resistance and hence improves HbA1c (Cho et al., 2019). 'Carbs & Cals' (Carbs&Cals, 2018) is an organisation who have developed resources for healthcare professionals to educate people with diabetes on carbohydrates in different food sources and is used widely in the UK and in other diabetes education programmes (Addington & Holcombe, 2017; Deakin et al., 2006; Khunti, Gray, et al., 2012b). DIME use 'carbs & cals' activities to facilitate dietary content.

6.4. What?

Table 6.1 outlines the content of each session in the current insulin start group and DIME. There are some activities from the current insulin start group in south London which are replicated in DIME: 'dose titration' (session 1) and 'quiz of last session' (session 2).

Additional activities included in DIME were underpinned by psychological techniques and adapted from previous diabetes education programmes, which are outlined later in this chapter (section 6.4.1.2). Psychological and behavioural strategies which were included in DIME but are not in the current insulin start group include: exploring perspectives (session 1; motivational interviewing technique); techniques for remembering insulin (session 1; behaviour change technique); review of progress since last time (session 2 and 3; behaviour change technique); relapses (session 2; cognitive behavioural therapy technique); and feedback on blood glucose reading and goal setting (session 2 and 3; behaviour change technique). Educational content which was identified from study 2 (chapter 3) which is included in DIME but not the current insulin start group includes diabetes complications (session 2); diabetes technology (session 2); weight and insulin (session 3); diet and carbohydrates (session 3); and exercise (session 3).

6.4.1. Materials

There were four different types of materials involved in DIME development including facilitator notes, workbooks, supporting materials, and printed materials.

6.4.1.1. DIME facilitator notes

A full version of the DIME facilitator notes can be found in appendix 6.2. The facilitator notes contain an 'introduction to the manual and instructions for use' detailing how the notes are to be used and guidance on booking venues which are convenient to the group members to maximise attendance.

In the DIME facilitator notes, text highlighted in green emphasises psychological skills (e.g. motivational interviewing, cognitive behavioural therapy), text highlighted in yellow shows group activities and text highlighted in purple shows homework tasks.

Subheadings display different topics within each session and subheadings are coded in different colours for each session to distinguish between them. At the beginning of each session, the DIME facilitator notes begin with 'You will need' with a list of materials needed in that session, 'introductions' to welcome the group and a session overview which describes the content to be covered in that session.

Key learning points are displayed in a box for each new educational content to ensure the facilitator consistently covers the same material. The key learning point covers all essential type 2 diabetes insulin educational and safety content as outlined by NICE guidelines (NICE, 2015).

Table 6.1-*Session content of current insulin start group and DIME*

Session	Current insulin start group content	DIME content
Session 1	• Introductions • Ground rules • Initial questions • Diabetes & the need for insulin • Safe insulin administration • Insulin storage • Self-injecting first dose • Insulin dose titration • Activity 1: Dose titration • Diabetes medications • Hypoglycaemia • Driving with insulin and employment • Blood glucose meter technique review	• Introductions • Ground rules • Exploring perspectives • Injection technique and checking blood glucose • Activity 1: Decisional balancing tool • Diabetes medication choice • What is diabetes and the need for insulin? • Activity 2: What's in it for you? • Hypoglycaemia • Dose titration • Activity 3: Dose titration • Driving and insulin • Techniques for remembering diabetes medication • Activity 4: Goal setting
Session 2	• Reflections & titration issues • Activity 1: Quiz of last session • Problems encountered • Sick Day rules • Travel • Annual Review & interpreting results • Next steps • Burning issues	• Introductions • Review of progress since last time • Activity 1: wheel of change • Relapses • Feedback on blood glucose reading and goal setting • Activity 2: Quiz of last session • Complications • HbA1c targets • Activity 3: Changes in blood glucose • Activity 4: Exploring importance of insulin • Sick day rules • Diabetes technology • Activity 5: Maintenance plan
Session 3	N/A	• Introductions • Review of progress since last time • Feedback on blood glucose readings and goal setting • What are carbohydrates? • Activity 1: Carb counting knowledge quiz • Weight, insulin & diabetes • Exercise and diabetes • How many carbs? • Types of carbs and glycaemic index • Ways to improve blood glucose • Activity 2: Thinking about carbs in our diet • Time restricted eating • Benefits of weight loss • Insulin on holiday

Some activities were outlined in the DIME facilitator notes and were not included in the workbooks as they were facilitator-led and designed to be completed by the whole group (other tasks outlined in next section were mostly completed individually or in pairs). For example, a cognitive behavioural therapy technique employed in the D-6 intervention which was included in DIME facilitator notes only is called 'changes in blood glucose' (session 2, activity 3). This activity involved working with unhelpful thinking styles, which is particularly helpful for people with depression. The activity addressed unhelpful thinking styles by identifying which factors relating to change in blood glucose and thinking about which of these factors are within or outside an individual's control. This helps address people who personalise or attribute negative outcomes to themselves (especially relevant for people with depressive symptoms). Another activity outlined in DIME facilitator notes only was 'exploring the importance of insulin' (session 2, activity 4). This activity helps facilitators judge the groups' readiness to change by using the 'readiness to change ruler' (a motivational interviewing technique). These are open questions and in this activity the group were asked where they might place themselves on a scale of 0 to 10 in response to the following questions:

- "How important is it to you to take insulin injections?"
- "How important is it to you to reduce blood glucose?"
- "How confident are you in reducing your blood glucose?"

Following these questions, the facilitator could ask a follow-up question: "Why do you place yourself at ___and, not 0?" to evoke change talk.

At the end of each session, the DIME facilitator notes encourage 'question and answer' time for the group to ask any questions, a description of next sessions content, and an outline of any homework tasks.

6.4.1.2. DIME workbooks and activities

DIME is supported by workbooks for people with type 2 diabetes in the group which outline activities in each session (appendix 6.3).

There were activities from MOVE-IT (Bayley et al., 2015) which were adapted for DIME which encompasses psychological techniques (table 6.2). For example, 'What's in it for you?' (session 1, activity 2) was an activity from MOVE-IT built on three questions to elicit change talk (motivational interviewing). The MOVE-IT intervention was based on cardiovascular risk, but was adapted for the DIME group to focus on starting insulin:

- Write down the top 3 reasons for starting insulin.
- What might happen if you don't take insulin?
- What changes would you see if you continued with insulin (now and in the future)?

Table 6.2-*Psychological techniques underpinning session activities*

Session	Activity	Diabetes education manual adapted from	Psychological techniques underpinning
Session 1	1: Decisional balancing tool	D-6	CBT*
	2: What's in it for you?	MOVE-IT	MI**
	3: Dose titration	Current insulin start group manual	
	4: Goal setting	MOVE-IT	MI**, CBT*, SCT***, operant conditioning
Session 2	1: Wheel of change	New	Transtheoretical model
	2: Quiz of last session	Current insulin start group	
	3: Changes in blood glucose	D-6	CBT*
	4: Exploring the importance of insulin	New	MI**
	5: Maintenance plan	MOVE-IT	MI**, CBT*, SCT***, implementation intentions
Session 3	1: Carb counting knowledge quiz	Carbs & cals	
	2: Thinking about carbs in our diet	New	MI**

*Cognitive behavioural therapy; **Motivational interviewing; ***Social cognitive theory

The MOVE-IT manual outlined 2 planning activities which were adapted for DIME. These were 'goal setting' (session 1, activity 4), and maintenance plan (session 2, activity 5). Planning is a motivational interviewing process to clearly identify next steps the group can take based on personal motivations e.g. 'Before the next session, my goal will be to….'. These planning activities also involved elements of cognitive behavioural therapy, for example problem-solving e.g. 'What might get in the way of achieving this goal?' and 'How can I get around this?'. Other psychological techniques underpinning the planning activities are social cognitive theory (social support) e.g. 'who can support me with this plan', and operant conditioning (positive reinforcement) e.g. 'if I achieve my goal, I will reward myself by…'. The facilitator is instructed to ensure rewards are realistic and would support behaviour change i.e. not just 'self-motivation', a list of potential rewards is listed at the end of the activity to help the group plan for these. Rewards may also be important for people with depressive symptoms. People with depressive symptoms may not reward themselves as they believe they are not worthy of them (Rehm, 1977), but rewards (e.g.

positive reinforcement an example of operant conditioning) can lead to successful behaviour change (Bandura, 1977).

Relapse prevention (cognitive behavioural therapy) is a component of the maintenance planning activity e.g. 'what situations might get in the way of achieving my goals' and 'if the above situations happen then what will I do to address these barriers to help me still achieve my goals?'. The latter question is structured as an 'if-then' statement (i.e. if this situation happens then…I will do this). This is known as an implementation intention (Gollwitzer, 1999) which helps transform intention into behaviour. One of the MOVE-IT activities included in the DIME session 1, goal setting activity 4 was 'readiness to change ruler' questions, a motivational interviewing technique to evoke change talk. The questions were:

- 'If I achieve this goal it will be…' (from not very awarding to extremely rewarding).
- 'How confident am I that I will achieve this goal?' (from not at all confident to extremely confident).

There were also activities adapted from the D-6 manual (Ismail et al., 2018). The 'climbing the mountain worksheet' used in the D-6 intervention uses a cognitive behavioural therapy technique known as 'graded hierarchy' to aid goal setting. This involves breaking down a goal into small steps and is thought to be useful for people who might find tasks overwhelming. This was included in DIME as part of a goal-setting activity in session 1. Also, people with depressive symptoms may find small tasks overwhelming, therefore this activity is good for breaking-down tasks into more manageable smaller steps.

The 'decisional balancing tool' is another D-6 activity which incorporates problem-solving (cognitive behavioural therapy) to firstly think of the pros of current diabetes treatment (without insulin), then the cons of current treatment, then think of the pros of insulin treatment to address the cons of current treatment (this is the core problem-solving component), and finally outline the cons of insulin treatment. The facilitator can then begin to address group concerns around insulin (another problem-solving element of the activity).

One activity selected from the 'Carbs and cals' (Carbs&Cals, 2018) range was the 'Carb counting knowledge quiz' (Carbs&Cals, 2019). This activity was useful to incorporate dietary content which was outlined as missing from current insulin start groups in south London (chapter 3, study 2).

A new activity designed for DIME was the second activity in session 3 called 'Thinking about carbs in our diet'. The group was encouraged to plan how they might swap carbohydrates for lower glycaemic index carbohydrates to prevent blood glucose spikes, as well as reducing the quantity of carbohydrates to help improve blood glucose control. The activity worked on the motivational interviewing principle that individuals could make a choice about what they would be happy to change in relation to diet, working upon their own motivations. In addition, the 'readiness to change ruler' questions (motivational interviewing) were asked so the facilitator could evoke change talk, for example 'rate how confident you would be to make these changes'. This was followed by comparing strategies amongst the group which might aid this behaviour change e.g. planning meals and snack ahead of time.

Activities which were adapted from the current insulin start group in south London were 'dose titration' (session 1, activity 3) and 'quiz of last session' (session 2, activity 2). The 'dose titration' activity was designed to check the groups understanding of how to adjust insulin doses based on morning blood glucose readings. It is important to encourage self-titration as this is associated with empowerment (Khunti, Davies, & Kalra, 2013) and improving insulin persistence (Misra et al., 2019). The 'quiz of last session' was useful to check the groups' memory of last sessions content and provide any missing information.

At the end of the workbooks for session 1 and 2, homework tasks are set out which include a blood glucose chart to record blood glucose readings every morning. This helps with adjustments in insulin dose.

6.4.1.3. DIME supporting materials

For all DIME sessions a board, A3 paper, pens and sticky notes were required to assist facilitators in explaining key educational content as well as addressing psychological concerns. For example, one cognitive behavioural therapy technique, which was adapted from the D-6 manual aids shaping behaviour and is known as 'keeping perspective' (session 2). This figure (figure 6.1) is drawn on the board and aims to normalise relapsing and prevent permanent relapse of engaging in a new health behaviour. This demonstrates the journey to success is built on improving and points of relapsing, however overall the person is improving despite periods of relapse. This technique encourages the group to think about their reaction to relapse and how to overcome it.

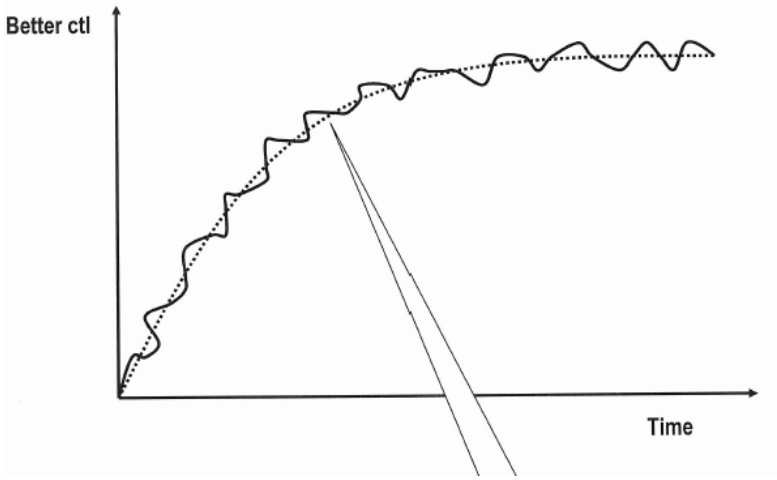

Figure 6.1-*Keeping perspective graph*

Session 1 requires the following materials to demonstrate an insulin injection: water pen and sponge. Recent research has found that if insulin injections have been demonstrated by a healthcare professional, the person with type 2 diabetes is less likely to delay insulin treatment (Polonsky et al., 2019). It is recommended the facilitator also takes a blood glucose meter to this session to demonstrate taking blood glucose.

Session 2 requires the following supporting materials: 'wheel of change', 'A3 outline of the body', and 'HbA1c meter drawing'. The 'wheel of change' involves taking the group through the stages of change from the transtheoretical model: pre-contemplation, contemplation, preparation, action, maintenance, and relapse (figure 6.2). The group are then asked at what stage they think they are at in terms of adopting insulin injections and blood glucose checking as part of their daily routine. This activity also supports the 'keeping perspective' demonstration (described above) in terms of thinking about relapse prevention. The 'A3 outline of the body' is used to elicit knowledge from the group regarding diabetes complications, the group are asked where on the body complications can occur and a sticky note is put there. Analysis of people who attended insulin start groups in study 2 (chapter 3) of this thesis found they would have liked more education around complications. Research has found providing personalised information about risk of diabetes complications is associated with improvement in HbA1c and diabetes distress. (Skinner, Barrett, Greenfield, & Speight, 2014). The 'HbA1c meter drawing' (appendix 6.2) illustrates where on the meter each group member is with their most recent HbA1c reading. Green on the meter equates to optimal HbA1c (30-58 mmol/mol), yellow means above target (58-78 mmol/mol) and red means suboptimal HbA1c (>78 mmol/mol). The meter is also a visual

representation of what their average blood glucose reading is based on their HbA1c reading. For people with type 2 diabetes, self-knowledge HbA1c is significantly associated with lower HbA1c than people with type 2 diabetes who do not know their HbA1c (Trivedi et al., 2017).

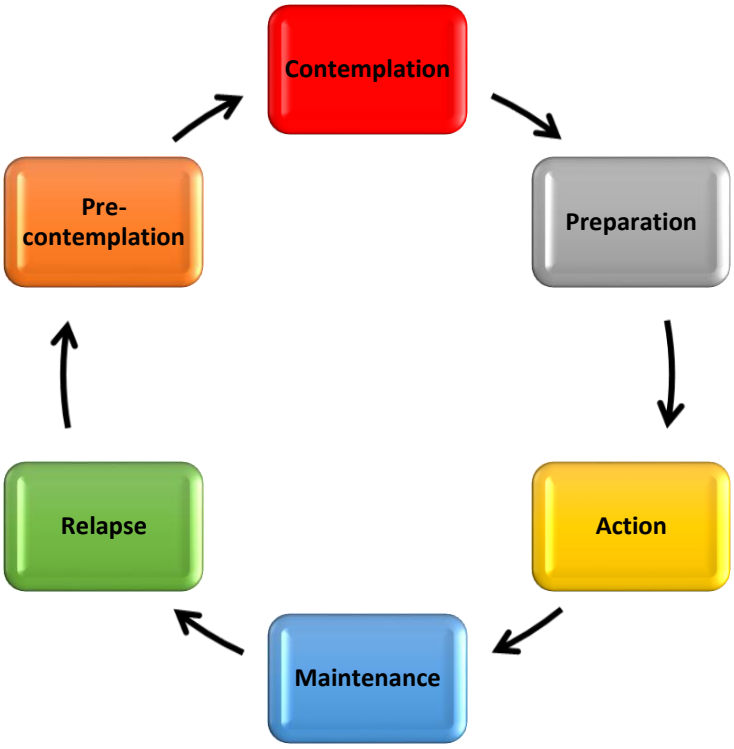

Figure 6.2-*The wheel of change*

For session 3 of DIME the following supporting materials are required: plastic food and plate, government eat well guide, and DIRECT liver scan. The plastic food and plate is used to help the group visualise how many carbohydrates they eat at mealtimes, the group then assesses whether they currently eat a 'high carbohydrate diet' (half plate contains carbohydrates), 'moderate carbohydrate diet' (25-40% of the plate contains carbohydrates), 'low carbohydrate diet' (25% or less of the plate contains carbohydrates), or a 'very low carbohydrate diet' (5-10% of the plate contains carbohydrates). This is compared against the governments eat well guide (Buttriss, 2016) which recommends a moderate carbohydrate diet. The reasons for these activities is to lead to a description of

the benefits of a low-carbohydrate diet e.g. promoting weight loss and improving HbA1c in type 2 diabetes (Bolla, Caretto, Laurenzi, Scavini, & Piemonti, 2019; Gannon & Nuttall, 2004; McArdle et al., 2019; Unwin & Unwin, 2014; Westman, Yancy, Mavropoulos, Marquart, & McDuffie, 2008). There are concerns over long term adherence to low carbohydrate diets (Bolla et al., 2019), therefore DIME uses motivational interviewing techniques to draw on individuals own motivation to change towards diet to increase adherence and promote overall healthy eating. The group are asked to discuss the benefits of weight loss, this is followed by a picture of the DIRECT liver scan to illustrate how weight loss can reduce fat around the liver (Lean et al., 2018).

6.4.1.4. DIME printed materials

The DIME intervention is supported by printed materials (appendix 6.4) for the group to take away from the sessions which outline all session content in a condensed easy-to-read file. The only printed material content which is not in the DIME sessions is a question and answer sheet on the myths around insulin injection therapy, several resources were reviewed and merged, in addition to discussion with thesis supervisors to create this resource (ADA, 2007; Brod, Alolga, et al., 2014).

6.4.2. Procedures

In the borough of Lambeth in south London people with type 2 diabetes who required insulin were identified in primary care and were referred to an insulin start group. To pilot test the newly developed DIME intervention, in the months of November 2018-January 2019 DIME replaced the current insulin start group. People with type 2 diabetes were referred as usual and the Lambeth Diabetes Team informed them via an information sheet (appendix 6.5) on the purpose of DIME, participants then consented (appendix 6.6) to take part in the pilot phase of DIME and were informed of the opportunity to be interviewed following the attendance of all three sessions. More information on the pilot testing of DIME is given in chapter 7 of this thesis.

6.4.2.1 DIME processes: Psychological skills

Key psychological techniques are highlighted in green in the facilitator notes. Here, a summary of the techniques with examples is provided.

Offering information and advice draws on the 'partnership' cornerstone of motivational interviewing. Previous research indicates people might already know up to 90% of health information of which researchers planned to tell them (Handmaker, Miller, & Manicke, 1999). Therefore, it is important to only offer the necessary information and not repeat what the group already knows in order to maintain group engagement. This can be

achieved through the 'elicit-provide-elicit' (E-P-E) technique. The facilitator 'elicits' what the group already knows about a topic, before 'providing' any unknown information or correcting misunderstandings. The final 'elicit' refers to checking the understanding of the information provided. This technique is also useful to 'chunk' information into manageable pieces which can aid memory (Ackermann et al., 2017). Impaired memory (Rose & Ebmeier, 2006) and concentration can be a bi-product of depression (Rock, Roiser, Riedel, & Blackwell, 2014; Rose & Ebmeier, 2006) therefore this technique could also be beneficial for people with depressive symptoms. The first example of the E-P-E technique in the facilitator notes is in session 1 when providing information around types of diabetes and the progression of type 2 diabetes, this technique is suggested for giving all educational information throughout the DIME facilitator notes. Another example of aiding group member memory in DIME was 'techniques for remembering insulin' whereby the facilitator encouraged a discussion of ideas for remembering to insulin and how this behaviour can become a habit i.e. taking insulin at a particular time in the same place every day. There is evidence for reminders being useful for people with type 2 diabetes to take insulin (Borah et al., 2009; Brod et al., 2012).

Another technique useful to offering information involves asking permission to talk about a topic, this is also encouraged throughout the DIME facilitator notes. This falls in line with the 'partnership' cornerstone of motivational interviewing as it initiates a collaborative style, and demonstrates respect (Steinberg & Miller, 2015).

Foundational practice skills (OARS) of motivational interviewing were encouraged by the DIME facilitator. Open questions provide an opportunity to explore the perspectives of the group, for example, asking "What is the one thing that drives you crazy about your diabetes?" (session 1). Open questions can also aid broadening perspectives of the group, such as in session 1 where group members explore the importance of insulin therapy, in addition to the facilitator exploring personal values to suggest why taking insulin could be important. For example, a personal value might be spending time with family, taking insulin helps feel less fatigued and improves wellbeing, allowing someone to be better able to spend time with family.

Affirmations are important when the group are describing and practicing techniques learnt in the group, for example, affirming correct insulin injection technique when practicing this behaviour in session 1. In session 2 and 3, when the group reflect on their progress since last session, this is an opportunity for the facilitator to provide reflections and summary

statements to check their understanding of something a group member has said as well as piecing together important information. Chapter 4 identified the need to consider people with type 2 diabetes and depressive symptoms, as they are more likely to initiate insulin sooner than people without depressive symptoms. People with depression are more likely to focus on negative aspects of themselves or the environment (Beck, 1967) and are more susceptible to repetitive negative thinking (i.e. interpretation bias) (Krahé, Whyte, Bridge, Loizou, & Hirsch, 2019). Affirmations are therefore important for people with depressive symptoms (and without) to highlight strengths and help increase self-efficacy. To increase confidence, DIME facilitator notes encourages the facilitator to use affirmations (including small changes) the people with type 2 diabetes have made between sessions, for example attempting to inject insulin or checking blood glucose.

Eliciting and activating change talk are part of the 'evoking' process of motivational interviewing which works on the principle that people are ambivalent about behaviour change. Motivation to change is known as 'change talk' and motivational interviewing helps people explore this. Motivational interviewing questions that help elicit change talk are known as DARN questions (Desire, Ability, Reasons, Need) and questions that activate change talk are known as CAT questions (Commitment, Activation, Taking steps). Examples of DARN-CAT questions which were adapted from D-6 for DIME are shown in table 6.3. DARN-CAT questions are in in all 3 sessions of DIME, after goal setting in session 1 and 2 to reflect on motivation towards personal goals, and after a 'walking' break in session 3 to reflect on motivation to exercise.

Cognitive behavioural techniques were also employed in DIME. As these cognitive behavioural therapy techniques are embedded within activities adapted from other diabetes education manuals, they are described in section 6.4.1.2. of this chapter.

Table 6.3- Motivational interviewing techniques: DARN-CAT questions

DARN (Desire, ability, reasons, need)	CAT (commitment, activation, taking steps)
D: What do you hope for your own health in the future?	C: So, what do you think you will do?
A: What one step might you be able to take to achieve this goal?	A: What might you be willing to do as a next step?
R: What would you say are three good reasons to achieve this goal?	T: What have you already done to attempt this goal?
N: What do you think you need to do at this point?	

6.4.2.2 DIME processes: Behaviour change techniques

Behaviour change techniques (derived from behaviour change wheel in chapter 5) were incorporated into all sessions of DIME. Table 6.4 outlines the behaviour change technique examples from each session and where it can be found in the DIME facilitator notes. Session 1 uses 38 behaviour change techniques, session 2 uses 21 behaviour change techniques, and session 3 uses 15 (table 6.5). The most frequently used behaviour change techniques overall are social support (unspecified) (n=20), goal setting (behaviour) (n=4), review behaviour goal(s) (n=4), instruction on how to perform the behaviour (n=4), and demonstration of the behaviour (n=4) (table 6.5). Social support (unspecified) was present in all sessions through motivational interviewing and counselling techniques.

6.5. Who provided?

The DIME intervention was designed to be delivered by diabetes specialist nurses who are the existing facilitators for the insulin start group in south London. They are appropriate to deliver the intervention owing to their knowledge and expertise in diabetes and insulin administration. Diabetes nurses would require additional psychological skills training (mainly motivational interviewing) to deliver the DIME intervention.

6.6. How?

The mode of delivery of the DIME intervention is face-to-face with supporting printed materials, and telephone follow-up calls (see chapter 5 'identify mode of delivery' for more information).

The number of people per DIME group is designed to be flexible. The group is designed for people within 1 month of insulin prescription to make sure people entering the group are at the same level in terms of familiarity with insulin therapy (see chapter 5 section 5.3.3.). Therefore, group sizes could vary depending on which people with type 2 diabetes have been prescribed insulin at the time of the group. The DIME facilitator notes accommodate for varying group sizes. For example, some activities benefit people working alone to complete worksheets to vary from group work, but if there is only a small group (e.g. 1-3 people) then these activities could benefit from the facilitator talking through questions and writing answers with the group.

6.7. Where?

The DIME intervention is to be delivered at a convenient location for the group of people with type 2 diabetes attending, for example, local general practice surgery, hospital or community venue.

Table 6.4- *Behaviour change techniques used in each 'new to insulin group' session*

Session	Behaviour change technique (BCTTv1 code)	Behaviour change technique example from DIME	Section of DIME facilitator notes
Introduction of DIME facilitator notes and instructions for use	Credible source (9.1)	delivered by a diabetes specialist nurse to emphasise the importance of insulin injection therapy to improve health (diabetes outcomes) and wellbeing.	Introduction
	Social support (unspecified) (3.1)	motivational interviewing, cognitive behavioural therapy techniques	Introduction
	Restructuring the physical environment (12.1)	arrange the group in a location and at a time which is easily accessible to those attending	Introduction
Session 1	Social comparison (6.2)	What have you heard from other people with diabetes who use insulin?	Exploring perspectives
	Information about others approval (6.3)	Discuss how family/friends will approve of insulin injections to improve health and wellbeing	Exploring perspectives
	Social support (emotional) (3.3)	Encourage they can bring someone to next group session if they wish.	Exploring perspectives
	Pros and cons (9.2)	Decisional balance tool: list pros and cons for current treatment (without insulin) and treatment with insulin.	Activity 1: Decisional balancing tool
	Problem solving (1.2)	Discuss barriers to insulin treatment. Discuss points to counteract barriers.	Activity 1: Decisional balancing tool
	Information about emotional consequences (5.6)	Insulin helps…improve well-being.	Key learning points 1.1: Barriers to insulin treatment
	Instruction on how to perform a behaviour (4.1)	Advise the group on steps for injecting insulin	Injection techniques & checking blood glucose
	Prompts/cues (7.1)	Suggest group use these steps (outlined in booklet to take home) so they can refer to whilst still learning.	Injection techniques & checking blood glucose
	Demonstration of the behaviour (6.1)	Demonstrate how to inject insulin using an insulin pen filled with water and sponge to inject into.	Injection techniques & checking blood glucose
	Behavioural practice/rehearsal (8.1)	Prompt group to practice insulin injection technique with water pen and sponge.	Injection techniques & checking blood glucose
	Feedback on behaviour (2.2)	Provide feedback on injection technique performance.	Injection techniques & checking blood glucose

Instruction on how to perform a behaviour (4.1)	Advise group on how to check blood glucose with their meter.	Injection techniques & checking blood glucose
Demonstration of the behaviour (6.1)	Demonstrate checking blood glucose.	Injection techniques & checking blood glucose
Behavioural practice/rehearsal (8.1)	Prompt group to practice checking blood glucose in group.	Injection techniques & checking blood glucose
Feedback on behaviour (2.2)	Provide necessary feedback on [blood glucose checking] technique.	Injection techniques & checking blood glucose
Information about the health consequences (5.1)	Explain that might experience hypo symptoms when blood glucose is dropping from high level but NOT at hypo level.	Hypoglycaemia
Action planning (1.4)	Encourage a plan to carry a hypo treatment when they are not at home.	Hypoglycaemia
Goal setting (behaviour) (1.1)	Set group goal of checking blood glucose every morning.	Dose titration
Information about health consequences (5.1)	Advise that it is better to inject the same time every day to prevent blood glucose spikes or hypos.	Dose titration
Instruction on how to perform the behaviour (4.1)	Advise group on how to titrate insulin doses.	Dose titration
Demonstration of the behaviour (6.1)	Demonstrate [dose titration] using examples	Dose titration
Behavioural practice/rehearsal (8.1)	Dose titration activity	Activity 3: Dose titration
Self-monitoring of behaviour (2.3)	Ask group to record daily, their morning blood glucose readings	Activity 3: Dose titration
Prompts and cues (7.1)	Discuss ideas for prompts/reminders for taking insulin.	Techniques for remembering diabetes medication
Action planning (1.4); Habit formation (8.3)	Prompt planning tasking insulin at a particular time every day in the same place.	Techniques for remembering diabetes medication
Social support (practical) (3.2)	If a group member has brought someone along with them to the group (family member/friend) then ask them to help remind to take insulin.	Techniques for remembering diabetes medication
Graded tasks (8.7)	Climb mountain sheet	Activity 4: Goal setting
Goal setting (behaviour) (1.1)	Get everyone to think of ONE goal they would like to work on before next session	Activity 4: Goal setting

	Non-specific reward (10.3)	Check they have set appropriate goals, challenge how they will remember to do this (qu3), and rewards.	Activity 4: Goal setting
	Social support (emotional) (3.3)	Suggest group could exchange contact details to provide support to each other if they want to.	End of session
Session 2	Focus on past success (15.3)	Discuss…1 thing you have achieved since last time (e.g. successes in injecting insulin or checking blood glucose in past week)	Review of progress since last time
	Review of behaviour goal(s) (1.5)	Review how well people are getting on with daily injecting insulin and checking blood glucose, address concerns, and modify goals if necessary.	Review of progress since last time
	Problem-solving (1.2)	relapse prevention	Activity 1: Wheel of change
	Verbal persuasion about capability (15.1)	Tell group they can successfully reduce HbA1c using insulin despite recent unwanted glucose readings/hba1c.	Relapses
	Feedback on outcome(s) of the behaviour (2.7)	Ask group whether think titration needs to happen based on readings	Feedback on blood glucose readings and goal setting
	Review of behaviour goals (1.5)	Modify insulin dose target (if needed).	
	Review of outcome goal(s) (1.7)	Modify goal for desired blood glucose morning readings if not yet achieving.	Feedback on blood glucose readings and goal setting
	Review of behaviour goals (1.5)	Review goal setting from session 1 task- examine how well group have performed in working on goals set in last session, modify future goal accordingly.	Feedback on blood glucose readings and goal setting
	Information about the health consequences (5.1)	Talk about how complications are caused and how they can be prevented by managing blood glucose (e.g. insulin injection).	Complications
	Goal setting (outcome) (1.3)	Discuss HbA1c targets.	HbA1c targets
	Biofeedback (2.6)	Inform each group member of their HbA1c reading and address how insulin injections might improve their reading.	HbA1c targets
	Salience of consequences (5.2)	Refer to HbA1c meter sheets- see if group knows where they are on the meter corresponding to blood glucose readings to highlight dangers of having high blood glucose readings.	HbA1c targets

	Re-attribution (4.3)	"Which of these factors [affecting blood glucose] are within your control and which are less easy to control or outside of your control?"	Activity 3: Changes in blood glucose
	Social comparison (6.2)	Ask more than one person in group (maintain group engagement)	Activity 4: Exploring importance of insulin
	Instruction on how to perform the behaviour (4.1) Demonstration of the behaviour (6.1)	Check confidence with checking blood glucose on their meters and demonstrate if required.	Diabetes Technology
	Action planning (1.4)	ACTIVITY 5: Maintenance plan	Activity 5: Maintenance plan
	Self-monitoring of behaviour and outcomes of behaviour (2.3 and 2.4)	Homework task: Blood glucose readings chart	End of session
Session 3	Feedback on outcome(s) of the behaviour (2.7)	Ask group whether think titration needs to happen based on readings.	Feedback on blood glucose readings and goal setting
	Review of behaviour goals (1.5)	Modify insulin dose target (if needed).	Feedback on blood glucose readings and goal setting
	Review of outcome goal(s) (1.7)	Modify goal for desired blood glucose morning readings if not yet achieving.	Feedback on blood glucose readings and goal setting
	Review of behaviour goals (1.5)	Review goal setting from session 2 task- examine how well group have performed in working on goals set in last session, modify future goal accordingly.	Feedback on blood glucose readings and goal setting
	Salience of consequences (5.2)	Use plastic food and plates to get group to represent how many carbs they are eating.	How many carbs?
	Goal setting (behaviour) (1.1)	Ask group to work individually on activity 2: "Thinking about carbs in our diet"	Activity 2: Thinking about carbs in our diet
	Social comparison (6.2)	List these changes they would be happy to make on board (e.g. might include swapping sugar/starch carbs to fibrous carbs, reduce quantity of carbs) to share ideas amongst group	Activity 2: Thinking about carbs in our diet
	Salience of consequences (5.2)	Produce DIRECT study liver fat picture (1 handout to pass around & on next page also) to highlight dangers of being overweight.	Benefits of weight loss

Table 6.5- *Frequency of behaviour change techniques within and between sessions*

Behaviour change techniques, BCTTv1 code	**Frequency of behaviour change techniques in Session 1**	**Frequency of behaviour change techniques in Session 2**	**Frequency of behaviour change techniques in Session 3**	**Overall frequency of each behaviour change techniques in all sessions**
Goal setting (behaviour) 1.1	3		1	4
Problem solving 1.2	1	1		2
Action planning 1.4	2			2
Review behaviour goal(s) 1.5		2	2	4
Review outcome goal(s) 1.7			1	1
Feedback on behaviour 2.2	2			2
Self-monitoring of behaviour 2.3	1	1		2
Self-monitoring of outcome(s) of behaviour 2.4		1		1
Biofeedback 2.6		1		1
Feedback on outcome(s) of behaviour 2.7		1	1	2
Social support (unspecified) 3.1	7	6	7	20
Social support (practical) 3.2	1			1
Social support (emotional) 3.3	1			1
Instruction on how to perform the behaviour 4.1	3	1		4
Re-attribution 4.3		1		1
Information about health consequences 5.1	2	1		3
Salience of consequences 5.2		1	2	3
Information about emotional consequences 5.6	1			1
Demonstration of the behaviour 6.1	3	1		4
Social comparison 6.2	1	1	1	3
Information about others' approval 6.3	1			1
Prompts/cues 7.1	2			2
Behaviour practice/rehearsal 8.1	3			3
Habit formation 8.3	1			1
Graded tasks 8.7	1			1
Pros and cons 9.2	1			1
Non-specific reward 10.3	1			1
Verbal persuasion about capability 15.1		1		1
Focus on past success 15.3		1		1
Total number of behaviour change techniques per session	38	21	15	

6.8. When and how much?

The current insulin start group in south London consists of 2 sessions 1 week apart. Session one focuses on key safety aspects of insulin administration, and session 2 reflects on any problems encountered as well as 'sick day rules' and travelling with insulin. Each session is around 2 hours.

Motivational interviewing sessions are designed to be 1-3 sessions (Rollnick & Miller, 1995). The DIME intervention was designed as 3 sessions to incorporate new content as well as allowing time for psychological techniques (such as motivational interviewing) to address fears and concerns around insulin and reduce ambivalence. The DIME intervention was designed to be offered within 1 month of insulin initiation (see chapter 6 'specify target behaviour' for more information). For DIME session 1 and 2 are 1-2 weeks apart and session 3 is 4-8 weeks later to allow time to adjust to insulin therapy and consider potential problems which can be addressed in the final session. Each session is 2 hours long.

6.9. Tailoring and modifications

The DIME intervention is a group intervention and therefore is not entirely personalised, however there are certain aspects which can be personalised for example discussing the action of insulin types can be applied to which insulin the group members were prescribed. The DIME intervention was piloted on 2 groups of people with type 2 diabetes newly prescribed insulin therapy (see chapter 7 for more information). Following each session, DIME could be adapted and modified based on how well the session went and feedback from the facilitator (KW) and observer (RU). These modifications could be made at any time during the pilot phase and after each session. Exit interviews of a sample of people who received DIME could also determine relevant modifications (chapter 7). All these modifications were made in advance of a feasibility randomised controlled trial (beyond the scope of this PhD thesis).

The following modifications were made following the pilot of session 1:

- Layout of DIME facilitator notes to aid ease of navigation for facilitator:
    - Fewer words per page
    - New topic on new page
    - Colour coding (activities, psychological techniques)
    - Boxes for key learning outcomes
    - Incorporate facilitator tools into handbook
- Consideration if only 1-3 people attended the group. Amend activities in this case e.g. can do as whole group out loud instead of in pairs or individually.
- Added in 'types of insulin' into this session.
- Added in driving (originally in session 3, needed for safety so moved to session 1).

- Added in Insulin Treatment Appraisal Scale to exploring perspectives if conversation stilted
- Added in Decisional balancing tool

The following modifications were made following the pilot of session 2:

- Swapped order of HbA1c and complications content to review complications first
- Add in spider diagram of blood glucose activity

The following modifications were made following the pilot of session 3:

- Added in use of plastic food and plates to represent how many carbohydrates group members are eating
- Added DIRECT study liver scan

More details on the modifications following exit interviews are provided in chapter 7.

6.10. How well?

Planned fidelity is to be examined in a feasibility randomised controlled trial (beyond the scope of this PhD). Audiotaping of DIME intervention sessions will be used to conduct fidelity assessment to a) demonstrate the facilitator is using behaviour change techniques and psychological techniques as intended (adherence), and b) whether these techniques were delivered at an adequate level (competence).

6.11. Chapter summary

The current insulin start group in south London and NICE guidelines for insulin education provided a starting point for the core educational content and safety information for the DIME intervention. The DIME intervention was underpinned by psychological theory and models including theory of planned behaviour, social cognitive theory, motivational interviewing, cognitive behavioural therapy, transtheoretical model, and the behaviour change wheel. Additional DIME content was included based on chapter 3 (study 2) interview responses on what people with type 2 diabetes desired in insulin education including information on: diabetes complications, diabetes technology, weight and insulin, diet and carbohydrates, and physical activity. Behaviour change techniques identified in chapter 2 (study 1) and chapter 5 (study 4) were incorporated into each session of DIME as appropriate to maximise behaviour change and aid insulin self-management. Chapter 4 (study 3) highlighted the importance of being aware of depressive symptoms in relation to insulin initiation and therefore DIME incorporates techniques which support people with depressive symptoms. The next chapter describes the pilot testing and evaluation of the pilot DIME intervention sessions.

Chapter 7 : *An evaluation of the pilot sessions of DIME*

7.1. Chapter scope

This chapter describes study 5 of this thesis which is a qualitative evaluation of views of people who attended the DIME pilot sessions and a quantitative case study report to assess potential improvement in biomedical outcomes following the DIME intervention (and initiation of insulin). This chapter also outlines modifications made to the DIME manual following exit interviews. The aim of this study was to determine the acceptability of the pilot DIME intervention.

7.2. DIME pilot

Three sessions of DIME were piloted on two different groups of people with type 2 diabetes who had recently initiated insulin (within 1 month of first insulin prescription) or were unsure about initiating insulin therapy but wanted to learn more. One person only attended the first round of DIME (all three sessions). Four people attended the second round of DIME, where 2 people attended all three sessions, 1 person did not attend the last session (reason unknown, difficult to reach), and the fourth person did not attend the 3rd session as they did not want to start insulin due to occupational reasons (bus driver). Modifications following each round of DIME are described in detail in chapter 5. The sessions were carried out at local general practice surgeries and a community venue within south London, a motivational interviewing trained diabetes specialist nurse (KW) facilitated the sessions and the sessions were observed by a PhD student (RU).

7.3. Methods

Interviews were one-off, semi-structured, and one-to-one of people who had attended all sessions of the DIME intervention. Ethical approval was obtained by King's College Hospital (ref: 17/LO/0363). This research was reported according to the consolidated criteria for reporting qualitative research checklist (COREQ) (appendix 7.1).

7.3.1. Recruitment and sample

During the first session of DIME, the group was asked if they were willing to be interviewed regarding their experience of DIME following attending all three sessions. People were purposively sampled if they had attended all three sessions so they could give feedback on content across the intervention.

7.3.2. Data collection

The topic guide was designed by 2 researchers (RU & KW) (appendix 7.2). Interviews were conducted by a female PhD student researcher (RU) who had observed the DIME intervention sessions and has had experience of conducting qualitative research. The interview was not piloted. Owing to the semi-structured nature of the interviews, the

interviewer provided prompts and additional questions which were not in the topic guide. Eligible participants were given an information sheet (appendix 6.5) and consent form (appendix 6.6) to consider, and if willing they were contacted via telephone by the researcher (RU) to arrange a convenient date and time. At the convenience of the interviewee, the interview location was offered at a King's College London research facility; or the participants' local general practice surgery. Friends or family of the interviewee were welcome to observe. Interviews were audiotaped and field notes were made immediately after the interview.

Interviewees were informed the study was funded by the National Institute for Health Research and the specific purpose of the project was to test a newly developed group intervention to help people with type 2 diabetes start insulin.

Interviewees consented to clinical data being obtained from their medical records regarding their diabetes treatment and biomedical outcomes pre and post DIME. Data built case studies for each interviewee including age, sex, ethnicity, diabetes treatment pre-insulin, insulin type (dose and frequency), HbA1c, blood pressure, estimated glomerular filtration rate (eGFR) and total cholesterol.

7.3.3. Data analysis

Inductive thematic analysis identified relevant themes within the anonymised data and was managed in NVivo12. The 6 stages of analysis were: 1) familiarisation of data (reading transcripts and making initial impression notes); 2) generation of initial codes (RU & ASM; reviewed by KW); 3) Collating codes to search for themes; 4) Review of themes and applying to coded data; 5) Defining and naming each theme; 6) Production of this PhD thesis chapter (chapter 7).

Case study data was qualitatively summarised. Independent sample t-tests were used to determine differences in biomedical outcomes (HbA1c, systolic blood pressure, diastolic blood pressure, eGFR, total cholesterol) pre and post DIME.

7.4. Results

7.4.1. Case study findings

Three people attended all three sessions of DIME and were all willing to be interviewed. The demographic and clinical information of the interviewees is outlined in table 7.1. The mean age was 60.33 (SD=4.04). All three interviewees were white males who attended their first session of DIME within 1 month of first insulin prescription and all were previously on 3 OADs before initiating insulin (including metformin and gliclazide).

Interviewee 01 and 03 started on intermediate-acting insulin (Humulin I) taken once per day before bed, which is recommended by NICE guidelines (NICE, 2015). Interviewee 02 started on premixed insulin (Novomix 30) taken before breakfast due to a post-prandial increase in blood glucose after breakfast. Interviewee 01 and 02 remained on their initial insulin type at 6-8 months follow-up (titrating dose up as required). Interviewee 03 changed insulin from intermediate-acting (Humulin I) to long-acting (Abasaglar) 8 months later due to HbA1c targets not being reached (79 mmol/mol), however, HbA1c increased since starting the long-acting insulin (85 mmol/mol), perhaps due to optimal titration not yet being reached. Interviewee 02 obtained optimal HbA1c target (<58 mmol/mol) at 4 months post-insulin initiation follow-up (48 mmol/mol) which was maintained at 9 months post-initiation (50 mmol/mol). Interviewee 01 remains above HbA1c target (94 mmol/mol) 11 months post insulin initiation, but overall HbA1c has reduced by 15mmol/mol since pre-DIME/insulin HbA1c test (109 mmol/mol).

Overall, there were no significant changes pre to post DIME in systolic blood pressure (p=0.34), diastolic blood pressure (p=0.84), eGFR (p=0.95), and total cholesterol (p=0.93). All were in target range for blood pressure (<140/90mmHg) pre and post DIME (NICE, 2019). Interviewee 01 and 02 had target eGFR (>90) pre and post DIME (NKF, 2013). Interviewee 03 presented eGFR of 60 pre and post DIME, so even though not in target there was no deterioration following DIME. Interviewee 03 had elevated total cholesterol pre-DIME (5.1) but this reduced post-DIME (4.2). For interviewee 01 and 02 total cholesterol remained in target (<5) pre and post DIME (NHS, 2019).

7.4.2. Exit interview findings

The average duration of interviews was 16.01 minutes. Inductive thematic analysis revealed three themes with further subthemes displayed below: self-management needs, group dynamics, and delivery needs (figure 7.1).

Table 7.1- *Case study data of DIME interviewees*

	Interviewee 01	**Interviewee 02**	**Interviewee 03**
Date of first DIME session	November 2018	December 2018	December 2018
Age (on starting insulin)	58	65	58
Sex	Male	Male	Male
Ethnicity	White	White	White
Diabetes treatment pre-insulin (starting month/year)	Metformin* (Jun 10) Gliclazide** (Oct 11) Sitagliptin*** (Aug 18)	Gliclazide** (Oct 15) Metformin* (Oct 15) Dapagliflozin**** (Dec 15)	Metformin* (Dec 12) Sitagliptin*** (Feb 13) Gliclazide** (Apr 18)
Starting insulin type (starting month/year), dose, frequency	Humulin I (Nov 18), 10 units, once per day (before bed)	Novomix 30 (Nov 18), 6 units, once per day (before breakfast)	Humulin I (Nov 2018), 12 units, once per day (before bed)
Current insulin type (date obtained: month/year), dose, frequency	Humulin I (June 19), 18 units, once per day (before bed)	Novomix 30 (Aug 19), 10 units, once per day (before breakfast)	Abasaglar (Jul 19), 74 units, once per day (before bed)
HbA1c (month/year)			
Pre-DIME	109 (Aug 18)	64 (Nov 18)	99 (Nov 18)
Post-DIME	114 (Jul 19) 94 (Oct 19)	48 (Mar 19) 50 (Aug 19)	72 (Mar 19) 79 (Jul 19) 85 (Sep 19)
Blood pressure (month/year)			
Pre-DIME	Systolic/Diastolic 122/80 (Aug 18)	Systolic/Diastolic 139/71 (Nov 18)	Systolic/Diastolic 140/75 (Nov 18)
Post-DIME	Systolic/Diastolic 124/67 (Apr 19)	Systolic/Diastolic 130/76 (Sep 19)	Systolic/Diastolic 130/80 (Jul 19)
eGFR (month/year)			
Pre-DIME	106 (Dec 18)	102 (Jul 18)	60 (Jul 18)
Post-DIME	94 (Apr 19)	110 (Aug 19)	60 (Jul 19)
Total cholesterol (month/year)			
Pre-DIME	2.9 (Dec 18)	3.4 (Jul 18)	5.1 (Nov 18)
Post-DIME	3.6 (Apr 19)	3.4 (Aug 19)	4.2 (Jul 19)

*1g twice daily; ** 160mg twice daily; ***100mg once daily; ****10mg once daily

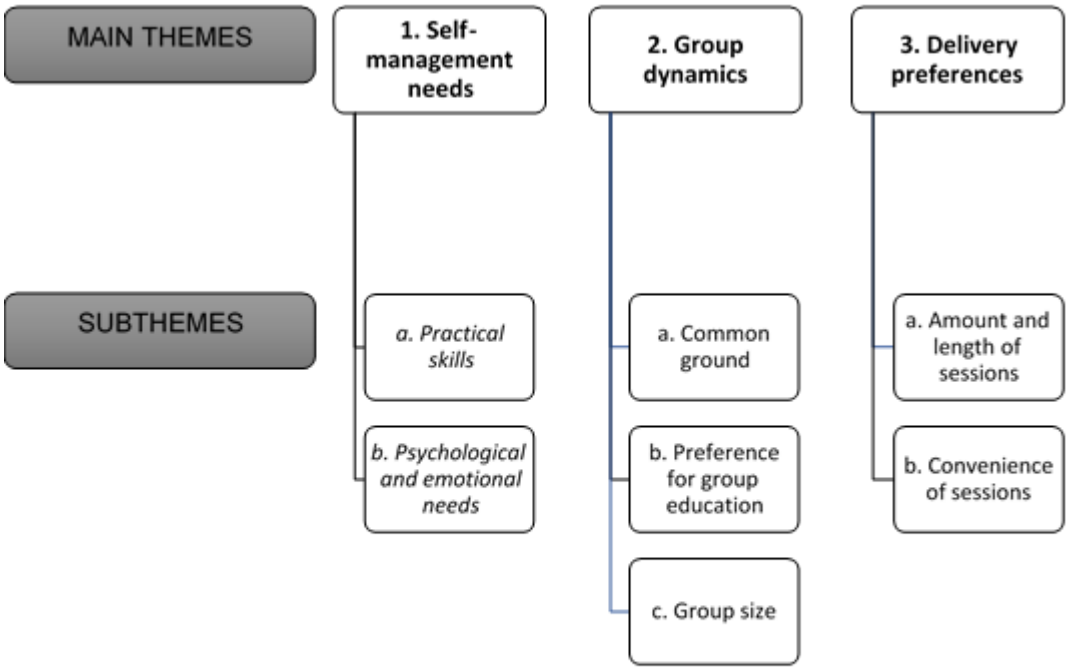

Figure 7.1- *Summary of themes and subthemes in study 5*

1. Self-management needs

The DIME intervention covered both practical demonstrations and practice relevant to insulin self-management as well as addressing psychological concerns of this treatment.

a. Practical skills

Interviewees valued learning practical insulin self-management skills such as learning how to inject:

> "*I was going on insulin just the practical side of it you know how to do it and things to bear in mind to do with the insulin*." (02)

They also described the challenges of initially self-administering insulin therapy but feeling better after practice:

"*I was a bit nervous at first and I scrambled a bit doing it myself, then I sort of got the hang of it because I don't think I was doing it entirely correctly but after a while, a bit of trial and error*." (02)

Other valued practical skills included self-monitoring blood glucose to direct insulin self-management in relation to adjusting doses:

"Keeping a record of my insulin and my blood sugar levels has led me to work out what it is that I'm doing wrong and that kind of thing." (03)

There was a preference for experience learning, for example, a walking activity to demonstrate the positive effects of exercise on blood glucose:

"I didn't feel that I was under any kind of pressure but I was surprised by how much my sugar levels have gone down. And if someone had told me to do that I ever thought yeah, of course, but yeah. Actually having done it and actually had it proved to me. I was I was amazed and that's really useful to know." (03)

One DIME attendee did not enjoy the walking activity but did appreciate the value of doing so:

"But I didn't think much of the walk [laughs]… you know its something to think about you know." (01)

A session that one interviewee anticipated not being useful was the third session which had content on diet as they had been to previous diabetes education sessions on this topic. However, once they attended this session, they realised it was useful and more applied to insulin self-management:

"*Strangely enough the one I thought would be least useful and I wasn't particular for was the last one which was mainly on food. Because I've had those sessions with various people before but in fact it was quite you know a good practical guide I thought."* (02)

There were some practical skills which were not covered in the pilot DIME intervention such as handling insulin on long term trips:

"*…you know how do you keep it [insulin] and you know it's ok if you are only going for a week or two of course but perhaps if you are going for longer [on holiday] …*" (02)

b. Psychological and emotional needs

Two people described the benefits of starting insulin such as the alleviation of fears, feeling better, and feeling in control of self-management:

> "*I was a bit scared about going on to the insulin of course but once on it, it seems quite routine."* (02)

> "*think I'm beginning to feel some of the benefits of having my blood sugar levels under control that that I wasn't aware. I didn't realize there would be. Quite so much of a change in how I felt."* (03)

> "*You know simple things like being in control of the amount that I give myself was something that took a little time to get used to but at the same time was quite liberating knowing that I could alter the amount if I needed to."* (03)

This was supported by the DIME facilitator who appeared to alleviate concerns around insulin initiation as well as provide reassurance that insulin can prevent long-term complications:

> "*There were questions obviously and concerns that I thought were addressed*." (01)

> "*… it has given me reassurance, type of thing, that if I did control my diabetes, I can lead a moderately, err, the worst, the effects of diabetes would be greatly reduced, so it's given me that reassurance. I am grateful for that*." (01)

Another interviewee described the positive communication style between the DIME facilitator and the group which did not rely on 'scare tactics':

> "*I didn't want a situation where you say if I didn't take the medicines…the consequences are….that way giving you a scary system or anything else I've learnt… I thought [the facilitator] came across as understanding and appreciated my problems."* (01)

There was evidence for the need for ongoing psychological support following the DIME intervention, for example, reassurance with administering correct insulin dose:

"I did need a bit of encouragement about that because I put it up originally from 6 to 8 [units] then to 10 but being still new at the game so to speak, I was a bit worried if I was doing the right thing" (02)

For one DIME attendee there seemed to be a burden of diabetes treatment and managing medications as well as insulin, which was not covered in the DIME intervention:

"…with the amount of drugs, I'm having, the tablets, it is, you know to me, it is a bit confusing…" (01)

2. Group dynamics

The format of DIME was a group; therefore, it was important to determine whether group dynamics were successful.

a. Common ground

There were reports of common ground amongst group attendees and interest in sharing experiences:

"*It was quite interesting to talk to the other people as well, as well as to get guidance on what to do. To compare, even though they might be on a different type of insulin, it's interesting to see the common ground*" (02)

"*I did find the talking with the other people who were in the group interesting. And helpful as well because that you were able to share experiences*." (03)

However, it was noted (though not a problem in their group) group harmony may depend on the personalities within the group:

"*I thought, well it depends who you're on it with but the people I was on with I think it went very well."* (02)

b. Preference for group education

One interviewee described initially wanting one-to-one education but through attending DIME realised the usefulness of a group to provide a broader perspective:

"*I wanted one-to-one with a nurse strangely, you know, it needs quite useful to get another opinion or somebody might want to point something out you hadn't thought of and indeed the nurse might not have considered*" (02)

Another found groups encouraging and would be interested in other exercise-based group education sessions:

> "*I like the idea of the encouragement you get from being in a group and if there was a similar kind of group that had more perhaps physical exercise or something like that built into as well. I would enjoy that.*" (03)

One group attendee preferred one-to-one education but was happy to attend a group situation if required:

> "*…my preference is on a one to one basis. I am not a team person that way, but if circumstances meant that I had to be in a group situation I was prepared to along with that*." (01)

One-to-one was preferred to address sensitive issues:

> "*So, there are probably things that are pertinent to me particular that didn't get covered but then I wouldn't have expected them to within a group situation.* " (03)

c. Group size

The group sizes of the DIME pilot were small as commented by interviewees:

> "*I think the first session there was supposed to be somebody else come along but that person did not attend*." (01)

One preferred a smaller group to give everyone a chance to contribute:

> "*I think that was the other point and a very small group. Yeah, if you get more than that [4 people in the group] you always risk the thing about it being somebody might dominate it or something and whereas, you know, there's there was good sort of, everyone was saying and equally contributing*." (02)

On the contrary, another preferred a larger group to have the opportunity to share more experiences and get a more 'rounded' viewpoint:

> "*I think if the group was bigger, it would be possible to perhaps get a more rounded, you know, there was two or three of us in that group and we were all doing different kinds of insulin at different times. And so, the experiences that we could share with were slightly limited*." (03)

3. Delivery preferences

DIME was delivered in 3 sessions lasting 2 hours each, one group at a community setting, and the other group at a local general practice surgery.

a. Amount and length of sessions

The length of the sessions seemed to be acceptable:

> "*I think the length of the sessions was about right*." (03)

However, one felt they could be half an hour shorter:

> "*They perhaps a little stretched out. I think perhaps an hour and a half rather than two hours."* (02)

Another commented positively on having a larger gap between the second and third DIME session to implement what has been learned:

> "*I think it's right to have break it in so you can think about what has been discussed. If it's all in one day, it's very difficult to handle the thing."* (01)

One urged for providing contact details of someone who could answer questions following the DIME intervention:

> *"What I'd like to think that if something occurred to me that I was unsure about that there would be someone that I could phone to ask*." (03)

b. Convenience of sessions

The DIME location was convenient for two attendees and timing even though they both needed to book time off work:

> "*the last two sessions I was able to get the time off work in order to do so. So that, that wasn't an issue… it's not too difficult for me to get here… there wasn't any issues about barriers or anything else or that*." (01)

> "*I have work but an hour and the location for me, it was very convenient. So I didn't have to come far at all. So that wasn't a problem.* " (02)

Even though they attended all sessions, the location was not ideal for one interviewee:

> "*I've got to say that the only gripe I had really with the sessions was where they were at and for me… even though it's not that far a distance is actually incredibly difficult. You know organising myself to be there at the right time was my main problem.*" (03)

7.5. Discussion

7.5.1. Summary of results

Analysis of exit interviews revealed mostly positive feedback towards the DIME intervention in relation to practical skills learned, psychological support received, finding common ground amongst DIME attendees, and acceptability of DIME delivery including amount and length of sessions, and convenience of sessions. In summary, all 3 interviewees have remained on insulin therapy 9 (or more) months post-initiation. Case study data revealed, even though 2 out of 3 interviewees remain above HbA1c target (>58 mmol/mol) post-DIME and insulin initiation, all improved HbA1c from pre-DIME test to most recent HbA1c follow-up (9-11 months insulin initiation). In addition, overall there was maintenance of other biomedical targets post-DIME (blood pressure, eGFR, total cholesterol).

7.5.2. Comparison to thesis study 2 findings

Chapter 3 (study 2) describes a qualitative evaluation of an existing insulin start group run in south London. There are some similarities themes drawn from chapter 3 and the current chapter 7 qualitative analysis. For example, chapter 3 found that peer support from the insulin start group was important to create a supportive environment. Likewise, in DIME, attendees found common ground and enjoyed sharing their experiences of managing diabetes. Chapter 3 refers to interviewees being keen for more peer support such as social activities. One interviewee in chapter 7 also comments on the desire for more peer support in the form of exercise sessions. Peer support is an important aspect of group education where previous research has demonstrated it is beneficial knowing other people with type 2 diabetes who are on insulin therapy (Bogatean & Hâncu, 2004a; Tan et al., 2011). The interviewees' desire for exercise-based sessions follows the 'walking activity' in session 3 of DIME which is a type of experience-based learning. This relates to Kolb's Experiential Learning Theory (Kolb, 1984) which suggests knowledge is created through experience. The walking activity was designed to demonstrate exercise can reduce blood glucose, which was successful in 2 out of the 3 DIME interviewees. Healthcare professional reassurance and taking time to address concerns is important for insulin adherence (Stuckey et al., 2018; Tang et al., 2018). The findings of this thesis chapter support the value of reassurance where the facilitator provided reassurance around injection technique (chapter 3) and that insulin prevents long term complications (chapter 7).

Chapter 3 indicated group dynamics were not managed well in some insulin start groups, and some expressed a preference for one-to-one education so questions could be

answered. One interviewee in chapter 7 felt that a small group would give a better opportunity for everyone to contribute, but on the contrary, another preferred a larger group to encourage the sharing of broader experiences. Hence, views of optimal group size appear to be mixed. Optimal group size for diabetes education is unknown and further research is required (Rickheim, Weaver, Flader, & Kendall, 2002) and group size depends on the type of people within the group, the type of diabetes education, the method of delivery, and facilitator preference (Mensing & Norris, 2003). Though on a whole, interviewees were positive about DIME, one interviewee in DIME suggested more sensitive issues should be addressed one-to-one indicating group education cannot address all concerns.

Even though there were similar themes between chapters 3 and 7, different conclusions were drawn in some cases. For example, chapter 3 found that not all insulin start group facilitators had the skills to address concerns around insulin, however, this did not seem an issue following DIME where communication style and alleviation of fears were positively commented on. One interviewee in DIME appreciated the facilitator not using 'scare tactics', for example, threatening with the risk of long-term diabetes complications. Research has long known that that health threat messages can cause defensive processing where people wish to protect their self-integrity, and therefore the threatening message is disregarded (Steele, 1988). Motivational interviewing, which is the psychological technique used in DIME, helps to reduce message defensive and increase message acceptance (Ehret, LaBrie, Santerre, & Sherman, 2015). Research has not evaluated whether this translates to behaviour in terms of persisting with insulin therapy in type 2 diabetes. Data from the case study of interviewees reveal they remained on insulin therapy at 9-11 months follow-up, which could be explained by motivational interviewing techniques increasing message acceptance promoting persistence to insulin therapy. Larger, powered studies are required to determine the reliability of these results.

Following either an insulin start group or DIME, there still appeared to be concerns around diabetes self-management. For example, following the insulin start group (chapter 3) there were still concerns around hypoglycaemia, injecting, the longevity of insulin, weight, and insulin, and social stigma. These concerns following the insulin start group were not reported post-DIME which could indicate this new intervention resolved some of these issues. However, there were still some concerns following DIME, for example, one reporting a burden managing multiple medications.

7.5.3. Exit interviews and DIME modifications

Exit interviews did outline some areas for improvement which led to modifications of the DIME manual summarised in table 7.2. For example, added content in relation to individualised education around medication regime and traveling with insulin on long trips. Other additions included exploring the importance and confidence of reducing blood glucose, the framing of session 3 i.e. dietary content relates to insulin which would not have been covered in previous diabetes education sessions, and set space for contact details for post-DIME queries. The final DIME manual can be found in appendix 6.2.

Table 7.2- *Modifications to DIME manual following exit interviews*

Exit interview quote	Modification to manual
Session 1	
"I don't know the name of it, the make of it." (01)	Making sure everyone in group knows the name of their insulin and what it does (e.g. long, intermediate or short-acting) as opposed to talking through the types of insulin generally.
"…with the amount of drugs, I'm having, the tablets, it is, you know to me, it is a bit confusing…" (01)	Talking through how other medications fits in with insulin regime and planning how to remember to take medications (individual plans).
Session 2	
"Keeping a record of my insulin and my blood sugar levels has led me to work out what it is that I'm doing wrong and that kind of thing." (03)	Explore not only importance of taking insulin but also importance in reducing blood glucose and confidence in reducing blood glucose.
"*Strangely enough the one I thought would be least useful and I wasn't particular for was the last one which was mainly on food. Because I've had those sessions with various people before but in fact it was quite you know a good practical guide I thought."* (02)	Emphasise the third DIME session on diet relates to insulin and diet, this content would not have necessarily been covered in other diabetes education groups.
Session 3	
"*…you know how do you keep it [insulin] and you know it's ok if you are only going for a week or two of course but perhaps if you are going for longer [on holiday] …*" (02)	Content on travelling with insulin on long trips.
"What I'd like to think that if something occurred to me that I was unsure about that there would be someone that I could phone to ask." (03)	Contact details for post-DIME insulin queries.

7.5.4. Strengths and limitations

One limitation is interviews were not returned to interviewees for comment, so interviewees did not have the opportunity to provide further insight. An advantage of this qualitative analysis over chapter 3's analysis is diabetes treatment pre and post insulin initiation (and DIME attendance) could be accounted for.

Recruitment to the pilot phase of DIME was limited due to the number of people with type 2 diabetes referred to the secondary care diabetes teams to initiate insulin at the time of recruitment. The DIME intervention was designed to be flexible in group size as it was assessed as more important for people with type 2 diabetes to access the DIME intervention at the appropriate time i.e. within 1-month insulin initiation, rather than waiting for a larger group size (for example n>4) when people might have been prescribed insulin at different times (for example within 1 month versus >1 month ago).

Interpretation of these findings is somewhat limited due to small sample size (n=3) which lacked diversity (all male, white ethnicity, all on similar OAD treatment before insulin initiation) contributing to poor information power. Lack of power and diversity in these results might limit the development of the next stage of the DIME intervention. However, owing to this only being a pilot phase, the findings are insightful towards modifying the manual for future feasibility randomised controlled trial. In addition, insights were strengthened by data analysis being conducted by two researchers with different backgrounds (health psychology and diabetes nurse). Future qualitative evaluation of DIME should adopt a larger sample size and increasing diversity by purposively sampling for age ethnicity, sex, and insulin treatment type; in addition to achieving information power based on study aim, sample specificity, quality of dialogue, and analysis strategy (Malterud et al., 2016). This would strengthen the interpretation of results, making them more generalisable to the population of people with type 2 diabetes, hence providing a stronger influence in the development of the DIME intervention.

Thereafter, a randomised controlled trial would be useful to determine whether the DIME intervention improves HbA1c, insulin adherence and persistence, and other outcomes over usual care.

7.6. Chapter summary

This initial qualitative evaluation of the pilot phase of DIME development revealed positive views of DIME attendees, improvements in HbA1c, and maintenance of other clinical outcomes. Therefore, at this stage DIME seems to an acceptable intervention for helping

people with type 2 diabetes start insulin. The interviewees revealed some areas of DIME which require improvement; hence the DIME manual has been modified considering these suggestions. This evaluation was useful to determine initial acceptability and to strengthen manual development for a future feasibility randomised controlled trial (beyond the scope of this PhD thesis).

Chapter 8 : *Discussion*

8.1. Overview

The overall aim of this thesis was to develop a group psychological intervention to optimise insulin initiation for people with type 2 diabetes. This new intervention was called DIME. This thesis covers the following MRC phases of developing and evaluating complex interventions: development (studies 1-3; chapters 2-4); and part of the piloting phase (study 4 and 5; chapters 6 and 7) (Craig et al., 2008), figure 8.1.

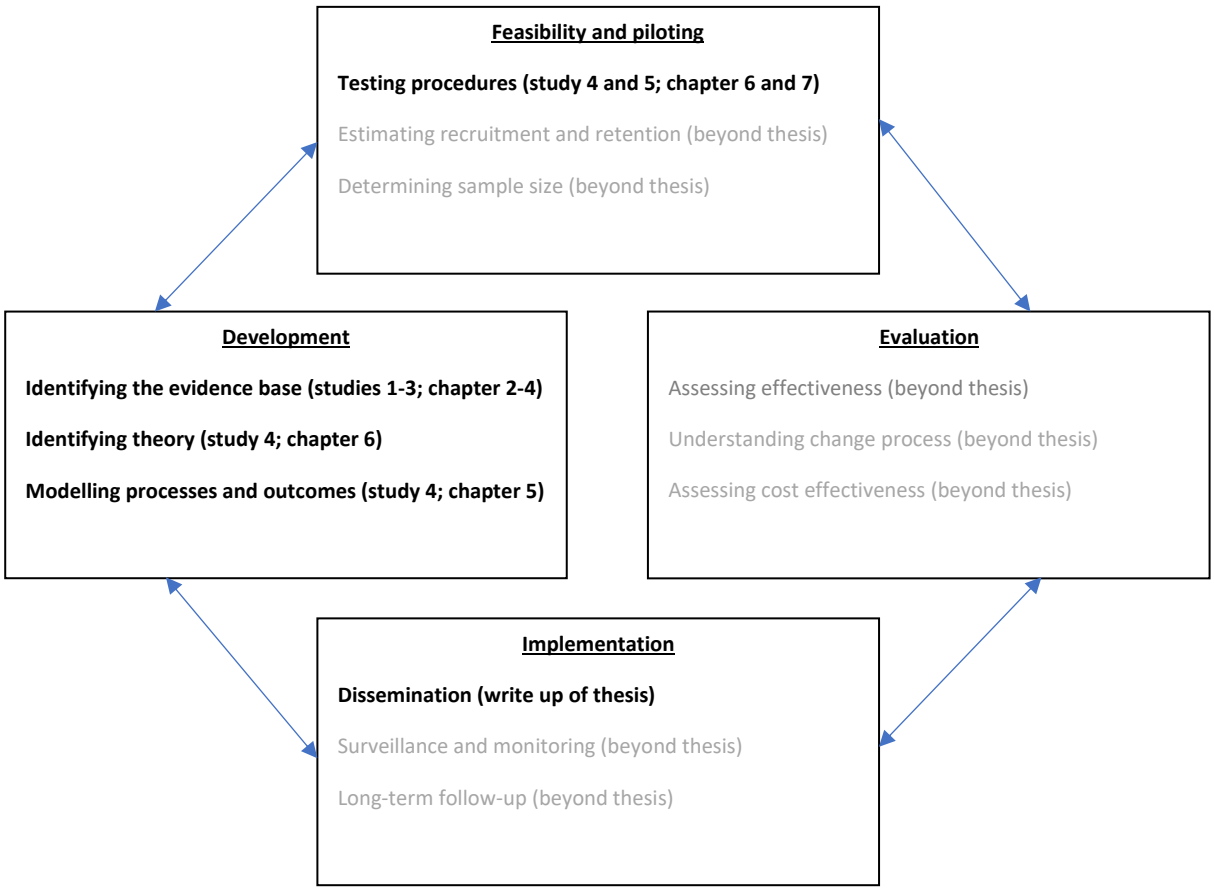

Figure 8.1-*MRC phases of developing and evaluating complex interventions: DIME*

8.2. Summary of Main findings

8.2.1. Study 1: A meta-analysis to determine the effectiveness of behaviour change techniques in psychological interventions to improve HbA1c for people with Type 2 diabetes mellitus.

Study 1 of this thesis was the first meta-analysis to examine an association between HbA1c and behaviour change techniques extracted from psychological interventions (n=67) for people with type 2 diabetes. Study 1 of this thesis demonstrated that HbA1c was significantly lower in psychological interventions compared to the control conditions. Across trials, 'social support', 'goals and planning', and 'feedback and monitoring' were the most frequently used behaviour change technique categories associated with improvement in HbA1c.

Although previous type 2 diabetes research has not extracted behaviour change techniques from psychological interventions, previous literature has extracted behaviour change techniques from other types of interventions including online self-management interventions (van Vugt, de Wit, Cleijne, & Snoek, 2013), behavioural interventions targeting physical activity (Avery, Flynn, Van Wersch, Sniehotta, & Trenell, 2012), interventions targeting both physical activity and diet (Cradock et al., 2017), and implementation interventions (Presseau et al., 2015). Unlike study 1 of this thesis, none of these previous studies performed a meta-regression between glycaemic control and behaviour change technique category.

Data extraction of behaviour change techniques in study 1 of this thesis was challenging. It might be expected that behaviour change techniques reporting might have improved over time since the introduction of the behaviour change technique taxonomy (Michie et al., 2015), however unclear reporting was evident regardless of the year of publication. This was important to consider in the development of the DIME intervention which clearly reported all behaviour change techniques (study 4) as well as additional psychological techniques according to the TIDieR checklist.

8.2.2. Study 2: Experiences of attending group education to support insulin initiation in type 2 diabetes- a qualitative study

Study 2 (chapter 3), a qualitative evaluation of an existing insulin start group in south London, indicated the need for improved psychological skills training for nurse facilitators of the insulin start groups to adequately address negative insulin beliefs and manage group dynamics. Even though not directly related to insulin education, previous research

indicated nurses benefited from psychological skills training in supporting people with type 2 diabetes (Graves, Garrett, Amiel, Ismail, & Winkley, 2016). Hence, the aim was to train DIME nurse facilitators in psychological skills to support the initiation and ongoing insulin self-management. Study 2 of this thesis specifically evaluates group insulin education, whereas previous research has only evaluated general type 2 diabetes education (Chatterjee, Davies, Stribling, Farooqi, & Khunti, 2018; Deakin, Cade, Williams, & Greenwood, 2006; Loveman, Frampton, & Clegg, 2008; Scain, Friedman, & Gross, 2009; Trento et al., 2010).

Practical demonstrations of insulin injection technique prevent delay in initiating insulin (Polonsky et al., 2019), likewise in study 2 of this thesis practical insulin demonstrations helped address fears of ongoing uptake of insulin therapy. This technique was taken forward in the DIME intervention design.

Previous qualitative work reports the positive and negative experiences of insulin initiation in people with type 2 diabetes (Holmes-Truscott, Browne, & Speight, 2016). Study 2 of this thesis sampled people with a similar duration of type 2 diabetes (around 11 years) but adds to the findings by exploring the impact of group insulin education and subsequent insulin self-management.

8.2.3. Study 3: Prospective study of the association between psychological factors at type 2 diabetes diagnosis and insulin initiation- South London diabetes (SOUL-D) cohort

Study 3 (chapter 4) was an 8-year primary care medical record follow-up of the SOUL-D cohort consisting of 1735 people with type 2 diabetes. Study 3 of this thesis study found a prospective association between depressive symptoms at type 2 diabetes diagnosis and shorter time to insulin initiation. Therefore, not only is depression more prevalent in people with type 2 diabetes than the general population (Ali, Stone, Peters, Davies, & Khunti, 2006; Anderson, Freedland, Clouse, & Lustman, 2001; Krishna, 2018; Moulton, Hopkins, Ismail, & Stahl, 2018), but depressive symptoms also impact ongoing treatment and bring forward the initiation of insulin treatment.

Previous research on the SOUL-D cohort found an association between baseline depressive symptoms and increased inflammation (Laake et al., 2014) and an association between depressive symptoms and 2-year follow-up macrovascular symptoms (Ismail et al., 2017). Study 3 of this thesis adds to these findings by finding a significant association between insulin initiation and, baseline macrovascular complications and depressive symptoms.

The findings from study 3 are unique and highlight the importance of considering depressive symptoms from diagnosis and throughout the progression and treatment of type 2 diabetes. Previous work has only studied the association between depressive symptoms in insulin-naïve populations of people with type 2 diabetes (Iversen et al., 2015; Nefs, Pop, Denollet, & Pouwer, 2013), and not from type 2 diabetes diagnosis. The DIME intervention took this into account by utilising psychological techniques that were considerate of people with depressive symptoms. For example, techniques derived from cognitive behavioural therapy which was initially developed to treat people with depression that have been used in previous type 2 diabetes interventions e.g. the D-6 (Ismail et al., 2018) and MOVE-IT (Bayley et al., 2015).

Study 3 of this thesis was also the first study to examine the prospective longitudinal association between diabetes distress and negative insulin beliefs, and insulin-related outcomes. Previous research has found an association between diabetes distress and negative insulin beliefs (Makine et al., 2009). In addition, negative insulin beliefs (otherwise known as psychological insulin resistance) have been commonly associated with a delay in insulin initiation (Ng, Lai, Lee, Azmi, & Teo, 2015). However, study 3 of this thesis did not find a significant association between these two psychological factors at type 2 diabetes diagnosis and insulin-related outcomes (after controlling for baseline confounders). However, the variables in this analysis were only baseline predictors (i.e. measured within 6 months of type 2 diabetes diagnosis). Negative insulin beliefs or diabetes distress developed later in the progression of type 2 diabetes might predict insulin-related outcomes. Therefore, as psychological insulin resistance is commonly reported as a barrier to insulin initiation elsewhere (Ng et al., 2015) as well as negative beliefs existing in people with type 2 diabetes who have already started insulin (Holmes-Truscott et al., 2016), the DIME intervention still aimed to address psychological insulin resistance to improve insulin self-management behaviours and subsequent glycaemic levels.

8.2.4. Study 4: The development of the DIME intervention

Study 4 describes the development of the DIME intervention detailed in chapter 5 (stages of the behaviour change wheel) and chapter 6 (reported according to TIDieR checklist) of this thesis.

There is evidence for the efficacy of general type 2 diabetes group-based education (Chatterjee et al., 2018; Davies et al., 2008; Khunti et al., 2012). Much evidence specifically exploring insulin education refers to one-to-one education sessions (Bala, Rusu, Moise, & Roman, 2019; Brod, Alolga, & Meneghini, 2014; Mathers et al., 2012; N Patel et al., 2015)

and none of these studies consider psychological aspects towards initiating as well as persistence or adherence to insulin treatment. The DIME intervention adds to the literature by developing a group-based insulin education, aiming to address psychological problems associated with insulin initiation and persistence/adherence to insulin.

The behaviour change wheel is a health psychology model integrating 19 behaviour change frameworks. The COM-B model (capability, opportunity, and motivation- behaviour model) is the centre of the wheel. The first three studies of this thesis identified that all the COM-B components should be targeted for insulin self-management to improve. For example, study 1 found the most frequently reported behaviour change techniques associated with improvement in HbA1c were 'social support', 'goals and planning', and 'feedback and monitoring' which can be linked to opportunity (i.e. social opportunity, e.g. having more people around injecting insulin), motivation (i.e. reflective motivation, e.g. goal setting in relation to managing with insulin therapy), and capability (i.e. psychological capability, e.g. self-monitoring blood glucose) components of COM-B, respectively. In study 2, the qualitative themes generated were linked to capability (ongoing self-management success e.g. knowledge and skills to initiate insulin), opportunity (need for more peer support e.g. having peer support to self-manage with insulin), and motivation (insulin concerns post-group e.g. confidence to inject and plans to do it) COM-B components. Study 3 indicates that depressive symptoms impact the initiation of insulin, therefore reducing depressive symptoms relates to the motivation (automatic motivation) component of the COM-B model. The final stages of the behaviour change wheel involve identifying specific behaviour change techniques (linked to COM-B components outlined) through which the DIME intervention was to be delivered, in addition to evaluating the appropriate mode of delivery.

The outcome of the behaviour change wheel led to a draft intervention strategy of DIME. In brief, the DIME intervention is a group-based nurse-led psychological intervention to optimise insulin initiation in type 2 diabetes (within 1 month of first insulin prescription). DIME is 3 sessions and is delivered at a local venue (general practice, hospital, community venue). Printed media and phone helpline support the DIME intervention. Twenty-seven behaviour change techniques were identified as relevant to the DIME intervention. The DIME intervention is also underpinned by psychological theory and models including the theory of planned behaviour (Ajzen, 1991), social cognitive theory (Bandura, 1991), motivational interviewing (Rollnick & Miller, 1995), cognitive behavioural therapy (Beck & Alford, 2009), and the transtheoretical model (Prochaska & Velicer, 1997). Combined, these

theories strengthen the development and delivery of the DIME intervention to optimise insulin initiation and self-management for people with type 2 diabetes.

8.2.5. Study 5: An evaluation of the pilot sessions of DIME

Study 2 of this thesis added to the literature by evaluating group-based insulin education which had not been previously examined, and study 5 (chapter 7) of this thesis further adds to the literature of evaluating group-based psychological insulin education. Study 5 of this thesis qualitatively (one-to-one interviews) and quantitatively (case study report) evaluated the DIME intervention pilot sessions. The qualitative evaluation found that DIME was overall acceptable to 3 people with type 2 diabetes who had attended all three DIME pilot sessions to initiate insulin. In addition, the case study report of the interviewees revealed improvements in HbA1c post DIME and maintenance of other clinical outcomes. Study 5 allowed for modifications of the DIME materials to strengthen overall development.

8.3. Clinical implications

The clinical implications of the research conducted in this thesis are as follows:

1. The behavioural change technique categories 'social support', 'goals and planning', and 'feedback and monitoring' should be the initial building blocks of type 2 diabetes education which aim to improve glycaemic levels (study 1 of this thesis).
2. Existing insulin start groups in south London and similar insulin group interventions worldwide require improvements, for example, psychological training for diabetes specialist nurses to help manage group dynamics and address concerns around insulin (study 2 of this thesis).
3. Where possible insulin group education should be offered to people with type 2 diabetes soon after first insulin prescription to enhance the group dynamic and shared experience (study 2 of this thesis). Therefore, group-based insulin education needs to be flexible in group size, for example, the DIME intervention is designed to admit people with type 2 diabetes within one month of first insulin prescription.
4. There is a need for education that is sensitive to people with depressive symptoms and type 2 diabetes in initiating insulin treatment. Depressive symptoms are prevalent throughout the progression of type 2 diabetes including bringing forward insulin initiation (study 3 of this thesis).
5. Insulin education for people with type 2 diabetes should be group-based to address issue of a declining diabetes specialist nurse population (DUK, 2016), and a growing population of people with type 2 diabetes (NHS, 2014). Diabetes group-based education is also more cost-effective than individual support (Yki-Järvinen et al., 2007).

Initial acceptance to the DIME intervention (study 5 of this thesis) provides a rationale for a psychological-informed group-based insulin education.

6. Psychologically-informed group-based insulin education could optimise insulin self-management for people with type 2 diabetes by reducing psychological insulin resistance and improving glycaemic levels (study 5 of this thesis). The DIME intervention aims not only optimising insulin initiation but providing skills and knowledge for ongoing insulin self-management. The implications being that insulin is the best treatment in type 2 diabetes for improving HbA1c (Davies et al., 2018; Nathan et al., 2009), and significantly reduces the risk of developing long-term diabetes complications (Caballero, 2009; Turner, Cull, Frighi, Holman, & Group, 1999; UKPDS, 1998). Not only can this be hugely beneficial to someone with type 2 diabetes in terms of positive physical and mental well-being (Holmes-Truscott et al., 2016; Holmes-Truscott, Skinner, Pouwer, & Speight, 2015), it also could significantly reduce costs to the NHS where a huge part of the budget is accounted for by treating diabetes complications (Hex, Bartlett, Wright, Taylor, & Varley, 2012).

The strength of these clinical implications and recommendations may depend on future research outlined in the next sections that would assess the feasibility and effectiveness of psychologically-informed group-based insulin education i.e. the DIME intervention.

8.4. Theoretical implications

The theoretical implications of the research conducted in this thesis are as follows:

1. This thesis is the first study to use the behaviour change wheel (theoretical framework) in the context of developing an insulin education group. Beyond this thesis, a randomised controlled trial involving the DIME intervention could determine whether the combination of behaviour change techniques underpinning DIME is effective over usual care in improving insulin self-management (i.e. uptake, adherence and persistence), reducing psychological insulin resistance, and improving glycaemic levels.
2. Reported behaviour change techniques in the DIME intervention can be utilised in future fidelity assessment. The BCTTv1 could be applied to transcripts of DIME sessions to determine which behaviour change techniques were delivered and if all behaviour change techniques described in chapters 5 and 6 of this thesis were delivered as intended (adherence) to an adequate level (competence). Fidelity assessment of

control conditions could determine contamination i.e. behaviour change or psychological techniques delivered in control (Magill et al., 2018).

3. Reported behaviour change techniques in the DIME intervention can also be used in a future process evaluation. A process evaluation would help explain how the DIME intervention works in improving outcomes. Following fidelity assessment of behaviour change techniques, an analysis could determine whether the combination of behaviour change techniques reported in DIME are associated with measured outcomes.
4. Behaviour change techniques are also useful in determining cost-effectiveness. For example, one study examined the cost-effectiveness of health behaviour-change interventions (Beard et al., 2019). The BCTTv1 was applied to 338 behaviour change intervention descriptions and regression analyses determined the association between behaviour change techniques and cost-effectiveness estimates (for example, quality-adjusted life years).

8.5. Recommendations for future research

Based on the findings of this thesis, the following recommendations for future research are:

1. Study 3 of this thesis, the long-term SOUL-D follow-up, analysed n=1003 participants medical records and found a significant association between depressive symptoms and insulin initiation after controlling for other baseline confounders. This supports following up the remaining participants in the cohort, there were n=1735 recruited at baseline, to add power to the analysis. A multi-level methods approach could be applied to additionally examine general practice-level data, for example, national diabetes audit data such as the size of general practice and performance indicators to determine whether these factors are associated with insulin-related outcomes. These findings could influence the future development of the DIME intervention.
2. The initial acceptability of the DIME intervention (study 5 of this thesis) provides a rationale for conducting a feasibility randomised controlled trial of DIME versus usual care (insulin start groups). A feasibility trial addresses components of the 'feasibility and piloting' MRC phase (Craig et al., 2008) which this thesis does not cover i.e. further testing of study procedures, estimation of recruitment and retention rates, and determination of sample size, figure 8.1.
3. Future qualitative work around the DIME intervention, i.e. following a feasibility randomised controlled trial, should aim for a diverse sample, achieving information power to maximise generalisability of findings that would help optimise DIME

intervention development and increase acceptability to a wider population of people with type 2 diabetes initiating insulin.

4. A diverse PPI group should be recruited to review DIME development so far (for example, the stages of the behaviour change wheel and review of the DIME manual) and influence future development. This would provide perspective from people with type 2 diabetes and strengthen the DIME development process (Staniszewska, Haywood, Brett, & Tutton, 2012).
5. A multicentred randomised controlled trial would be the next step following feasibility testing and would address the following components of the MRC phases: assessing effectiveness, understanding change process (i.e. process evaluation), and assessing cost-effectiveness (Craig et al., 2008).
6. A long-term follow-up of a randomised controlled trial would further aid implementation (dissemination, surveillance and monitoring, and long-term follow-up). Future long-term follow-up of the DIME intervention should consider why there are previously reported difficulties with long-term efficacy of general type 2 diabetes group-based education (Khunti et al., 2012; Norris, Lau, Smith, Schmid, & Engelgau, 2002). For example, to prevent poor long-term outcomes, optimal contact post-intervention should be evaluated without compromising cost-effectiveness (Khunti et al., 2012; Norris et al., 2002).
7. Previous research has indicated more work is needed to support people with type 2 diabetes in managing insulin long-term (Fulcher, Roberts, Sinha, & Proietto), hence future research involving the DIME intervention should aim to optimise long-term insulin self-management by considering plans for insulin intensification.

8.6. Strengths and limitations

A strength of this thesis is the reflexive research design which involved perspectives from a multidisciplinary team involved in different aspects of the thesis (outlined in detail in the 'reflexivity statement') for example, diabetes nurses, a health psychologist, psychiatrists, and a statistician. This minimises bias that influences different stages of the research process. Another strength is the use of mixed-methods primary research to inform the development of DIME which increases the validity of the intervention. DIME was evidence-based and underpinned by existing theoretical concepts. Using existing theory connects the research to existing evidence that guides new research, it also helps to describe an intervention and to explain why an intervention might be associated with an outcome of interest. Throughout this thesis standardised guidelines (PRISMA, COREQ, TIDieR) were

used to report the research which aids clarity, and transparency of reported methods and findings.

Study 2 highlighted the need for culturally appropriate resources to support group insulin education in type 2 diabetes which supports previous research that has recommended culturally appropriate interventions for people of ethnic minority (Machinani, Bazargan-Hejazi, & Hsia, 2013). However, tailoring insulin group education for people of different cultural backgrounds, and religious beliefs can be difficult (Rebolledo & Arellano, 2016). A limitation of DIME is that printed materials are still not equitable to all as only available in English language. This could be addressed in future research following testing of DIME in a randomised controlled trial.

The pilot phase of DIME, similar to previous studies exploring insulin education interventions (Bala et al., 2019; Brod et al., 2014; Mathers et al., 2012; Naina Patel et al., 2015), does not evaluate subsequent insulin uptake behaviour (adherence or persistence) following the intervention. Again, this could be tested in a randomised controlled trial. Even though DIME aims to address the psychological aspects of insulin use, it does not address healthcare professional clinical inertia nor systemic barriers. Therefore, future research should consider a broader intervention targeting insulin initiation in type 2 diabetes.

In south London, general practitioners in primary care were more likely to send people with type 2 diabetes to diabetes education who were achieving HbA1c targets than those who were not (Kirsty Winkley et al., 2016). This could also translate to insulin group education, and therefore healthcare professional barriers to sending people with type 2 diabetes group education need to be addressed. There are barriers for people with type 2 diabetes attending general group-based education (Coates, Slevin, Carey, Slater, & Davies, 2018; Horigan, Davies, Findlay-White, Chaney, & Coates, 2017; Mc Sharry et al., 2019; K Winkley et al., 2015), in addition to healthcare professionals barriers (Mc Sharry et al., 2019; K Winkley et al., 2018), and system barriers (Coates et al., 2018; Murphy et al., 2018). Hence, this is further support for multifaceted interventions not only to support insulin initiation but to encourage attendance at group-based insulin education. DIME currently does not address all of these barriers.

8.7. Overall conclusions

This thesis designed a new group psychological intervention to optimise insulin initiation for people with type 2 diabetes called DIME. The development of DIME was informed by

study 1) a meta-analysis of psychological interventions to improve HbA1c in type 2 diabetes; study 2) a qualitative evaluation of an existing insulin start group in south London; and study 3) a prospective cohort of newly diagnosed people with type 2 diabetes to determine an association between psychological variables (depressive symptoms, diabetes distress, and negative insulin beliefs) and time to insulin initiation. All provided support for DIME to be developed as a psychological intervention. These three studies determined all elements of the COM-B model (of the behaviour change wheel) needed to change to influence improvement in insulin self-management. This thesis found that psychological-informed group-based insulin education, the DIME intervention, was initially acceptable to people with type 2 diabetes who attended the pilot sessions. This provides a rationale for future development and testing of the DIME intervention to evaluate the effectiveness of improving glycaemic control, persistence, and adherence to insulin treatment, and the cost-effectiveness of the intervention.

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Appendices

Appendix 2.1: Psychological interventions to improve glycaemic control in type 2 diabetes: a systematic review and meta-analysis manuscript.

Title: Psychological interventions to improve glycaemic control in type 2 diabetes: a systematic review and meta-analysis.

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Abstract

Background: The quality of evidence that psychological interventions are effective in improving glycaemic control for adults with type 2 diabetes (T2D) is weak.

Purpose: We conducted a systematic review and meta-analysis of psychological interventions in T2D to assess whether their effectiveness in improving glycaemic levels has improved over the past 30 years. We applied the protocol of a systematic review and aggregate meta-analysis conducted to January 2003. We added network meta-analysis (NMA) to compare intervention and control group type against usual care.

Data Sources: MEDLINE, CINAHL, PsycINFO, EMBASE, Cochrane Controlled Trials, Web of Science, and Dissertation Abstract International were searched January 2003-July 2018.

Study Selection: Only randomized controlled trials (RCT) of psychological interventions for adults with T2D reported in any language were included. The primary outcome was change in glycaemic control (glycated haemoglobin, HbA1c (mmol/mol)).

Data Extraction: Data were extracted from study reports and authors contacted for missing data.

Data Synthesis: 94 RCTs were eligible for inclusion in the systematic review since the last review. In 70 RCTs (n=14,796 participants) the pooled mean difference in HbA1c in those randomised to psychological intervention compared with control group was -0·19 (95% C.I. -0·25 to -0·12) equivalent to a reduction in HbA1c of 3·7 mmol/mol with moderate heterogeneity across studies (I^2=64·7%, p<0·001). NMA suggested probability of intervention effectiveness is highest for self-help material, cognitive behavioural therapy, and counselling, compared with usual care.

Limitations

There is a possibility that some studies may have been missed if diabetes did not appear in the title or abstract.

Conclusion:

The effectiveness of psychological interventions for adults with T2D have minimal clinical benefit for improving glycaemic control.

Registration: International prospective register of systematic reviews (PROSPERO) registration, CRD42016033619.

Funding Source: National Institute of Health Research Health Technology Assessment.

Introduction

In type 2 diabetes (T2D), management involves adopting multiple self-care tasks which include consuming lower energy dense diets, increasing physical activity, self-administration of oral and injectable therapies, self-monitoring of blood glucose levels and decision-making about dose of insulin, attending education and annual review appointments.

Despite evidence based guidelines,(NICE, 2017) at least a third of people with T2D do not achieve target HbA1c levels.(NDA, 2018) This is partly attributable to psychological factors that adversely affect self-management. These include depressive disorders,(Anderson et al., 2001) anxiety disorders,(Grigsby, Anderson, Freedland, Clouse, & Lustman, 2002) and diabetes specific distress, such as fear of diabetes complications, hypoglycaemia,(Wild et al., 2007) insulin,(Brod et al., 2009) disordered eating,(Allison et al., 2007) the burden of living with T2D and stigma.(Polonsky, Fisher, Earles, et al., 2005) Psychological treatments, such as cognitive behavioural therapy (CBT) and counselling, including motivational interviewing, are offered with the aim of improving self-management. In 2003, we conducted a systematic review and meta-analysis of randomized controlled trials (RCT) testing the effectiveness of psychological interventions to improve glycaemic control in T2D. We found that there was a small but clinically significant reduction in HbA1c by 8mmol/mol.(Ismail et al., 2004) At that time, there were only 12 studies with a pooled sample of 522 participants, most were published before Consolidated Reporting of Clinical Trials (CONSORT),(Moher, Schulz, Altman, & Group, 2001) and were of low methodological quality. Since then guidance for conducting and reporting complex interventions have been published and widely disseminated, and there has been an explosion in the number of RCTs. The aim was to conduct a systematic review and meta-analysis to assess the effectiveness of psychological treatments as compared with control conditions in improving glycaemic control in adults with T2D and whether the strength for the association was improving over time.

Methods

We repeated the original protocol for the systematic review and aggregate meta-analysis for the primary outcome, change in glycated haemoglobin (HbA1c).(Ismail et al., 2004) We added network meta-analysis (NMA) to enable us to compare all intervention arms and attention control groups with usual care and expanded the data extraction to include

further details about the intervention that allow for potential replication, the protocol is available at: https://www.journalslibrary.nihr.ac.uk/programmes/hta/1421310#/. (Hoffmann et al., 2014),(NIHR, 2019). The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement,(Moher, Liberati, Tetzlaff, & Altman, 2009) and relevant extensions were followed.

Data Sources and Searches

MEDLINE (OVID), CINAHL, PsycINFO, EMBASE (OVID), Cochrane Controlled Trials Database, Web of Science, and Dissertation Abstracts International were searched from 1st January 2003 to 1st July 2018. (Our earlier review searched literature from inception of electronic databases to January 2003). Conference proceedings from Diabetes UK, American Diabetes Association, European Association for the Study of Diabetes, and International Diabetes Federation were searched for the past five years (from 2012 to 2018). We checked the US government trial registry (clinicaltrials.gov) and searched publication status for any ongoing RCTs. Finally, reference lists of included studies and other reviews were searched for additional studies and leading experts and investigators of ongoing RCTs identified from clinical trials registers were contacted for additional information. Web of Science (formerly Web of Knowledge) launched in 2002 and clinicaltrials.gov became widely mandated from 2004 onwards and Dissertation Abstracts International, a leading international repository since 2008, therefore these data sources were additional to those specified in the original protocol.(Ismail et al., 2004)

We used the Cochrane collaboration's optimum search strategy. The following terms were applied to search MEDLINE, 'diabetes mellitus', 'psychological therapies' and 'mood disorders', and 'clinical trials' and adjusted for other databases (Appendix 1, Table S1). We included additional keywords for some newer therapies, such as 'Acceptance Commitment Therapy (ACT)', and 'Mindfulness'.

Study selection

Studies eligible for inclusion were RCTs of a psychological intervention as defined previously for adults (age 18 years and older) with T2D. There was no language restriction. Psychological interventions were categorised as: supportive or counselling therapy, including motivational interviewing; CBT, including techniques commonly used in CBT such as relaxation, cognitive re-structuring, goal setting, problem-solving; and psychodynamic or interpersonal psychotherapy. We were mindful that newer therapies may have been

developed and may not fall into these criteria. Studies which did not explicitly describe the intervention or techniques, or which did not have face validity for these categories underwent consensus discussion by an academic liaison psychiatrist, health psychologist and nurse therapist trained in motivational interviewing (KI, RU, KW respectively). If agreement could not be reached, the study was excluded. Comparators were defined as usual care, waiting list, and attention control (matching the number of sessions as in the intervention arm) and diabetes education.

The main outcome was change in glycaemic control using HbA1c (mmol/mol) between baseline and follow-up (closest to 12 months). HbA1c was an inclusion criterion for the review.

All titles and abstracts of identified articles from the search were screened by two independent reviewers (RU and KW) to determine if they met the inclusion criteria. Full-text articles were accessed, and inter-rater reliability conducted to determine agreement for inclusion. If there was a disagreement at title and abstract screening, then the study was included for full-text screening. Quasi RCT, N-of-1 and any design other than RCT were excluded.

Data Extraction and Quality Assessment

Data was extracted independently by both reviewers (RU and KW). The data extraction form was managed in Microsoft Excel, piloted independently on 5 included studies and compared amongst reviewers before applying to the rest of the studies. Studies written in a language other than English were translated and data extracted by a native speaker. If there were multiple publications, the main one reporting the baseline and follow-up closest to 12 months was included. When studies involved more than one psychological treatment, data from the most intensive psychological treatment was included for the aggregate meta-analysis. Intensity was defined as number and duration of sessions (hours) and duration of the therapy (months). Data from all allocations (including alternative intervention, for example self-help material and control treatments) were extracted for the NMA. Missing data were requested from the authors. Any disagreements were discussed with a third reviewer (KI) until consensus was reached. We extracted data in a standardised format for: country of origin, and year. Data extracted on participant characteristics were summary estimates and included: age, gender, ethnicity, glycaemic control at baseline and at follow up, duration of T2D, type of diabetes treatment, duration of follow up. When studies included type 1 and type 2 diabetes, only data on T2D was extracted if the data had been

stratified by type. The characteristics of all interventions was coded as type, duration, number of sessions, mode of delivery (individual, group, family), therapist characteristics (profession), manualised treatment, and duration of follow up. In line with developments in methodology for complex interventions,(Hoffmann et al., 2014) we extracted information on underpinning psychological theory and data describing fidelity to the intervention and competency of the therapist.(NIHR, 2019)

We changed the quality assessment from original protocol to the Cochrane Risk of Bias tool as this had greater validity(Higgins et al., 2011) to determine high, low or unclear RoB,(Higgins et al., 2011) within and across studies. RoB was conducted independently (RU and KW) and disagreements were resolved by a third reviewer (KI). A subgroup meta-analysis was conducted by RoB rating, and meta-regression compared effect sizes between RoB groups.

Data Synthesis and Analysis

For the aggregate meta-analysis, the standardised mean difference (SMD), Cohen's d, was calculated to determine change in HbA1c (mmol/mol) between baseline and 12-month follow-up or closest to that data point. SMDs were pooled in random effects meta-analysis. SMDs were converted to absolute HbA1c values by multiplying SMD by pooled SD of all studies included in the meta-analysis. Diagnostic analyses included investigations of: the effect of removing individual studies; Egger's publication bias; and funnel plots(Egger et al., 1997) and trim and fill procedure(Duval & Tweedie, 2000) to determine potential for missing studies. Meta-regression was conducted if there were five or more studies with data that could be pooled.(M Borenstein, 2011) All meta-analyses were conducted using STATA 14 (StataCorp, College Station, TX, USA).

Non-protocol analyses were performed. For example, meta-regressions for the association between HbA1c and, primary outcome category; HbA1c primary outcome (versus HbA1c secondary outcome); comorbid depression inclusion criteria (versus no comorbid depression criteria); suboptimal HbA1c inclusion criteria (versus no suboptimal HbA1c inclusion criteria). In addition, meta-regressions were performed to determine the interaction between depressive symptoms as an inclusion criterion and whether HbA1c was the study's primary or secondary outcome; and the interaction between studies with suboptimal HbA1c as an inclusion criterion and whether HbA1c was the study primary outcome.

To determine the potential for cohort effects we linked the data from the original meta-analysis removing any duplicate studies.

For the NMA we analysed direct and indirect effects of the treatment and control arms on the mean change in HbA1c.(Riley et al., 2017) Indirect effects compared categories of intervention (psychological interventions, alternative treatments) or control groups (usual care, attention control, waiting list, diabetes education) within and across studies. We constructed network plots for direct comparisons. We conducted random effects meta-analysis allowing for heterogeneity and inconsistency between the studies.(Higgins et al., 2012; White, Barrett, Jackson, & Higgins, 2012) Inconsistency was assessed by comparing direct and indirect effects of the contrast I-J and Wald tests. Hedges' g formula was used to determine unbiased SMDs corrected for degrees of freedom for different categories of intervention with usual care as the control.(White & Thomas, 2005) Finally, we estimated potential ranks for each category using cumulative probability plots and surface under the cumulative ranking (SUCRA), the higher SUCRA (closest to one) the greater probability the intervention is effective.

Role of funding source

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Results

Study selection

We identified 31,069 study citations from the literature search (figure 1). Once duplicates were removed, titles and abstracts of 23,080 citations were screened from which 547 full texts were selected for further extraction. There was 94·5% agreement for identifying abstracts for full retrieval (Cohen's kappa=0·95). We identified 94 RCTs that met the inclusion criteria for the systematic review and reasons for exclusion of the other studies is given in figure 1.

Study characteristics

The studies included in the systematic review are listed and the study and intervention characteristics are synthesised in table 1. There was a broad range of clinical settings and/or criteria such as sub-optimal glycaemic control (n=28), specific duration of diabetes (n=19), age (n=41), body mass index (n=10) and depression (n=11). The were no RCTs administering a psychodynamic therapy, 33 RCTs administered CBT or techniques that fall under its umbrella such as relaxation therapy or problem solving, 60 RCTs delivering counselling, and one used interpersonal psychotherapy (IPT). In the control group, there were 60, 20, 10 and 4 studies, administering usual care, attention control, waiting list, and diabetes education respectively. Most therapists were diabetes specialists (n=37) or psychologists (n=31), and other (n=24) defined as research assistants (n=10), non-diabetes health professionals (n=11), lay people (n=3), or did not report their profession (n=2). Most interventions were delivered face-to-face (n=75), and mostly to individuals (n=54) and groups (n=37). The mean number of therapy sessions offered was 7.41 (SD 4.60); the mean duration of each session was 1.40 hours (SD 1.03); and mean duration of therapy was 5.44 months (SD 6.54). Twenty-seven studies referred to an intervention manual of which 7 provided a link to the manual, 24 studies provided a link to the study protocol.

Risk of bias within studies

Of those studies included in the meta-analysis, few were assessed as high RoB (n=3). The majority of studies were either of low RoB (n=29) or unclear RoB (n=38) (figure S1) and there was no association between these RoB categories, and HbA1c (p=0.23).

Results of individual studies

Additional information regarding the case definition of studies included in the meta-analysis is summarized in table S2. There were 70 RCTs with data to be pooled, giving a total sample of n=14,796. In the random effects meta-analysis, while there was a statistically significant reduction in HbA1c for those randomized to a psychological intervention compared to the control group (SMD -0.19, 95% CI -0.25 to -0.12, p<0.001), this was of weak clinical significance representing an absolute reduction in HbA1c of 3.7 mmol/mol (figure 2). Removal of individual studies had little impact on the overall effect size. There was moderate heterogeneity across studies (I^2=64.7%, p<0.001) and evidence of publication bias towards positive findings via Egger's test (p=0.002). No additional studies were considered missing using trim and fill method.

Synthesis of results

There was no significant difference in effect size (p=0.12) between interventionist categories when sub-group analyses were conducted for interventions delivered by psychology professionals (n=23, SMD=-0.30 , 95% CI=-0.46, -0.14, p<0.001, reduction in HbA1c, 5 mmol/mol), diabetes specialists (n=30, SMD=-0.18 , 95% CI=-0.25,-0.10, p<0.001, reduction in HbA1c 3 mmol/mol), and 'other' interventionists (n=16, SMD=-0.07 , 95% CI=-0.21, 0.06, p=0.29, reduction in HbA1c, 1 mmol/mol). Heterogeneity was high and significant for psychology professionals (I^2=72.6%, p<0.001), and moderate for diabetes specialists (I^2=57.7%, p<0.001), and 'other' interventionists (I^2=58.2%, p=0.002). For diabetes specialist delivered studies there was some evidence of publication bias (p= 0.01), but no additional studies were identified as missing using the trim and fill method. For psychology professional and 'other' interventionist delivered studies there was no evidence of publication bias (p=0.09, p=0.69 respectively), and no additional studies were identified as missing using trim and fill method.

There was no dose response association with number of sessions (b=-0.0063 [95% C.I. : -0.0224 to 0 .0097], p=0.43), or duration of the psychological intervention (b=-0.06 [95% C.I.:--0.18 to 0.07], p=0.36), or control group (b=-0.02 [95% C.I.:- -0.11 to 0.08], p=0.75).

Additional analyses, non-protocol

We conducted some additional non-protocol analyses. We categorised studies into 4 groups according to their primary outcome (table S3) HbA1c (n=33), psychological (n=19 [diabetes empowerment n=1, depressive symptoms n=11, diabetes distress n=4, self-efficacy n=2, stress n=2]), self-management behaviours (n=13 [physical activity n=6, medication adherence n=5, diet adherence n=2]), or biomedical (n=5 [coronary heart disease risk n=1, weight n=3, BMI n=1). There was no association between type of primary outcome and change in HbA1c (p=0.33). A meta-regression revealed no significant difference in effect size in HbA1c reduction between studies where HbA1c was a primary outcome (n=33) compared with studies where HbA1c was a secondary outcome (n=37), p=0.21.

Sixteen out of the 70 included studies had an inclusion criterion for depressive symptoms i.e. where participants had T2D with comorbid depressive symptoms (figure 2). A meta-regression revealed no significant difference in effect size in HbA1c reduction between studies with comorbid depression inclusion criteria versus studies where there were no

comorbid depression inclusion criteria (p=0.80). For 6 of the studies with comorbid depressive symptom inclusion criteria, HbA1c was the primary outcome (table S4). A meta-regression was conducted for the interaction between depressive symptoms as an inclusion criterion and whether HbA1c was the study's primary or secondary outcome, there was no significant difference between groups (p=0.63). Additionally, some of the comorbid depression studies included collaborative care interventions and as these could be considered distinct from other psychological interventions so we conducted a sensitivity analysis and there was no difference in overall effect size (SMD=-0.19, 95% CI= -0.26 to -0.13).

More information regarding inclusion/exclusion criteria of studies included in the meta-analysis can be found in table S5.

Eleven studies had an inclusion criterion for suboptimal glycaemic control (HbA1c 7.5%/58mmol/mol or more), figure 2. A meta-regression revealed no significant difference in effect size in HbA1c reduction between studies where suboptimal HbA1c was an inclusion criterion versus studies where suboptimal HbA1c was not an inclusion criterion (p=0.62). For 8 studies with suboptimal glycaemic control as the inclusion criterion, HbA1c was the primary outcome (table S6). A meta-regression was conducted to determine the interaction between studies with suboptimal HbA1c as an inclusion criterion and whether HbA1c was the study primary outcome, and there was no significant difference between groups (p=0.51).

Risk of bias across studies

The RoB domain which was most difficult to assess RoB criterion across studies (i.e. coded as 'unclear RoB') was the 'blinding of participants and personnel' domain (figure S2). 'Selective reporting' and 'other bias' RoB domains were mostly coded as low RoB, 'Random sequence generation,' 'allocation concealment' and incomplete outcome data' showed high RoB across studies.

Additional analyses: Cohort effect

To examine whether there was a cohort effect, we pooled the HbA1c data from 12 RCTs included in an earlier meta-analysis (from inception to January 2003) with the current review (January 2003 to July 2018), totalling N=82 RCTs (N=15,306). We derived a similar effect size to the current review (SMD -0.20, 95% CI=-0.26 to -0.14, p<0.001, equivalent to

absolute change in HbA1c of -4 mmol/mol). The effect size was not significantly different between the two meta-analyses (b -0.13 (95% C.I. -0.38 to 0.12), p=0.31).

Additional analyses: Network meta-analyses

For the NMA there was data available from 70 studies, which included 5 categories of psychological intervention and 3 control conditions. 146 treatment arms in total were analysed (some studies had more than one intervention or control group) with a total sample size of 15,702 (table S7). A network plot for all studies demonstrated that 13 out of a possible 28 contrasts could be analysed (figure S3), although to reduce over-estimation of treatment effects we only analysed contrasts with 2 or more studies. IPT and diabetes education (control) were only studied once and were thus removed from the network meta-analyses, including the control group for IPT, resulting in a total number of studies of 142 with a total sample size of 15,573 allowing us to study 11 out of a possible 15 contrasts.

Therefore, direct and indirect effects between CBT, counselling, self-help material (alternative intervention treatment), usual care, attention control and waiting list control were performed. Table S8 shows that the estimated direct and indirect effects between interventions did not differ significantly with only one exception (counselling versus self-help materials). The non-significant chi^2 test for inconsistency (chi(8) 8.33, p=0.402, I^2=3.9%) supports the conclusion of model consistency.

Table S9 shows the results of the consistency network meta-analyses comparing all treatments (and controls) against usual care. Self-help material (this was an additional treatment arm, used in 4 studies), CBT, and, counselling showed a small to moderate treatment effect. Table S10 presents pairwise comparisons of all treatment effects.

The rankogram (figure 3), indicated that self-help material had the highest probability of being the most successful intervention (58.1%), followed by CBT (22.4%) and counselling (18.8%.) while waiting list control, attention control and usual care were less likely to be the best treatment (all ≤0.6%). However, an assessment of mean rank and SUCRA suggests little differences between self-help materials, CBT and counselling (table S11).

Conclusions

In this study 94 RCTs were included in the systematic review, and 70 had HbA1c data which could be pooled and there was a statistically significant improvement in glycaemic control but this was of weak clinical significance. The absolute reduction in HbA1c of 3.7

mmols/mol is just less than the consensus minimal difference of 4 mmol/mol to reduce risk of microvascular and cardiovascular disease.(Baxter et al., 2016) The NMA demonstrated that CBT and counselling interventions were effective compared with controls but effect sizes were small. Self-help was offered as an alternative treatment to CBT (n= 1,268) or counselling (n=6,105) in four studies and this was effective but the total sample size was smaller (n=792). There was no difference in the change in glycaemic control when interventions were delivered by mental health or non-mental health professionals. Most studies were conducted in North America and Europe.

The strengths of this systematic review were that it was protocolised, registered with PROSPERO, conducted according to PRISMA guidelines, and not restricted to English language publications. We used aggregate and network meta-analysis to optimise the analysis of the pooled data. As we used the same protocol, we were able to link current data with a previous meta-analysis to compare effects of psychological interventions over 30 years.

The limitations of this review are that by using an older protocol we may have missed some innovative studies, and clinical settings such as multi morbidity and digital interventions where diabetes may have not appeared in the title or abstract. We used outcome data closest to 12 month follow-up as the majority of the included trials were of short duration. We did not review the contents of the manuals as there was no systematic method to do so. We included collaborative care interventions under the CBT umbrella and it could be argued that collaborative care is a complex intervention which differs from other psychological interventions. However, when collaborative care studies (Chwastiak et al., 2017; Ell et al., 2011; Williams et al., 2004) were removed from our overall aggregate meta-analysis there was no significant change in the results.

Our observation is that in the past 15 years there has seen an almost 10-fold increase in the number of RCTs testing the effectiveness of psychological interventions to improve glycaemic control as primary or secondary outcome, yet their effectiveness has decreased compared to pre-CONSORT studies. This needs discussion within the diabetes and mental health research and clinical community. Similar patterns of increasing research productivity yet decreasing effectiveness have been observed by others but has not until now been debated.(Ekong & Kavookjian, 2016; Pillay et al., 2015; Xie & Deng, 2017) One explanation is that despite guidance on the assessment for fidelity to the psychological intervention,(Gearing et al., 2011) there is little evidence that this is conducted. Deviations

in fidelity to a psychological intervention can lead to dilution of the 'dose' and underestimation of its effect. Another possible explanation is the lack of data on the level of proficiency or competency in the delivery of psychological treatments.(Gearing et al., 2011) A third explanation is whether primary focus of the psychological treatment is targeting glycaemic control. Only a quarter of studies had links to additional materials or manuals that would give information on specific contents of the intervention. Only a third of the studies were focused on glycaemic control. A significant proportion focused on treating depressive symptoms or weight with the secondary outcome that this would improve glycaemic control. We also noticed there was no difference in the effect on glycaemic control by the profession of the therapist. One interpretation is that diabetes specialists bring diabetes knowledge which is likely to be an important prerequisite for a therapeutic alliance for a person with diabetes. On the other hand, the mental health profession brings psychotherapeutic skills which is also a prerequisite for building a therapeutic relationship. These skills may be more effective when combined. A fifth explanation is that the intervention in the control was of high standard, usual care for diabetes has improved and the national average HbA1c has dropped in some countries.(Ali et al., 2013; NDA, 2018) Last but not least, as the methodological quality has improved with only a handful of RCTs assessed to be of high risk of bias, another explanation is that collectively these types of interventions, namely CBT and counselling, are not indicated in T2D. The average number of sessions were seven and the average duration of the intervention was approximately five months. T2D is a progressive condition and if a person is not able to make the self-management changes alone or with standard support, it is possible that they are unlikely to do so with a brief relatively inexpensive psychological intervention.

This review highlights a need for a balanced debate. On the one hand there is a clear policy agenda for integrating physical and mental health in diabetes but there needs to be psychological interventions that are effective in improving blood glucose, as ineffective interventions could do more harm and cost health systems more. National and international research strategy led by funding organisations need to invest in innovations in psychological treatments, rather than replicating existing psychological models that are repeatedly delivering very small effect sizes. For instance, there were no studies that used psychodynamic models, or addressed the high levels of disordered or addictive eating patterns, stigma of diabetes, or habit formation.(Gardner & Rebar, 2019)

In summary, brief psychological interventions in T2D have limited clinical effectiveness in improving glycaemic control.

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Disclosure statement

KW has served as a consultant or speaker for MSD and Valotech, SRH has served as a consultant for Lilly, Novo Nordisk, Takeda, Boeringher Ingelheim, Mannkind, Sanofi, Zealand Pharma and UN-EEG. He is a recipient of an award from the NIHR to evaluate a complex intervention, DAFNEplus, designed to improve glycaemic control in adults with type 1 diabetes. KI has received honorarium for educational lectures for Janssen, Sanofi, Eli Lilly and Novo Nordisk.

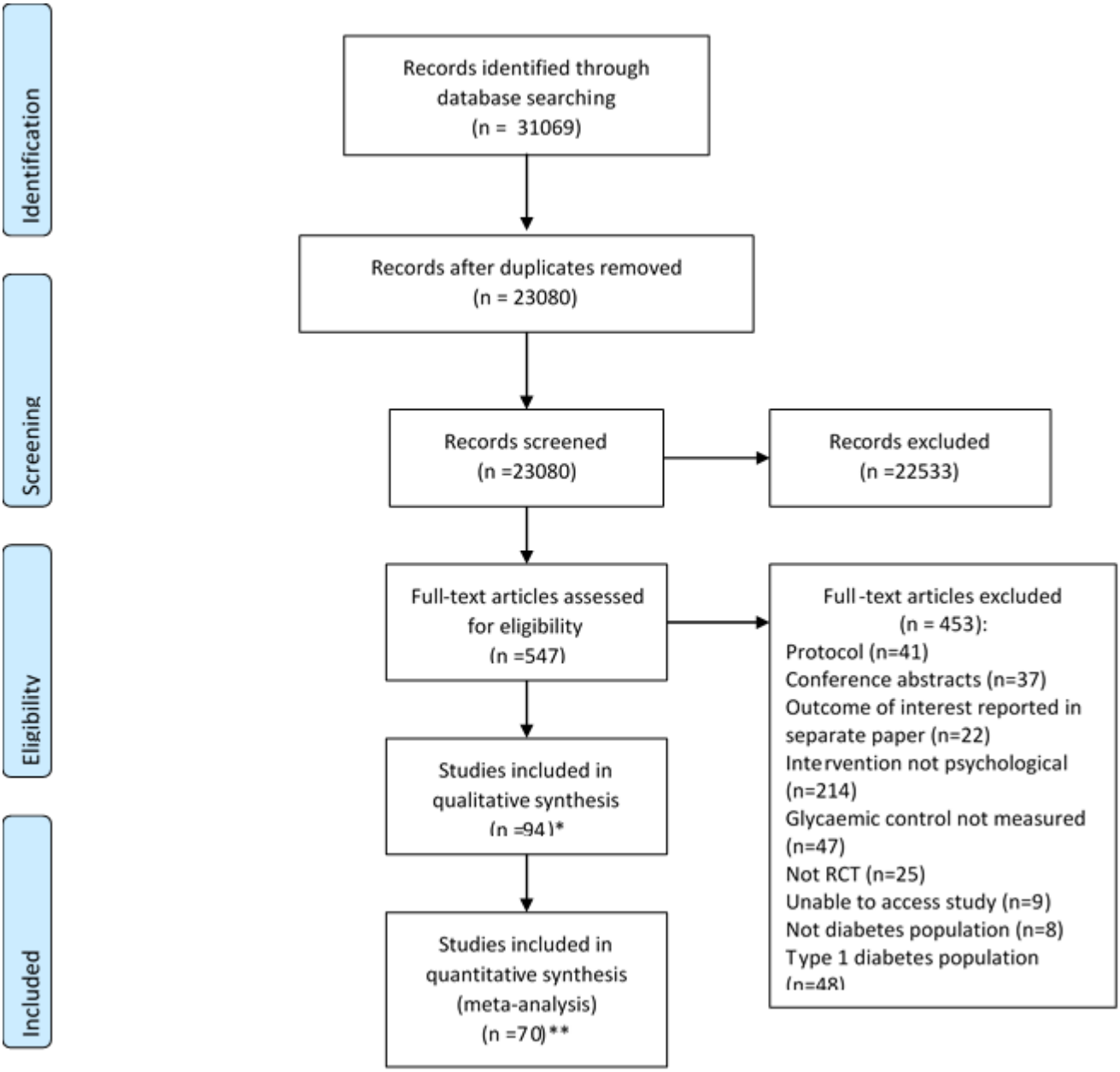
Author contributions

KW & KI conceived the study and DS, SH, & AB made substantial contributions to the study design. RU conducted literature search. KW & RU acquired study data. RU, DS & DP conducted data analysis. KW, RU, DS & DP interpreted data. RU and DS produced figures.

KW wrote the manuscript with substantial contributions, critical review and revision of the manuscript from RU, DS & KI. DP, SH & AB provided critical review and revision of the manuscript.

All authors provided final approval for the publication of the manuscript.

All authors agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of the work are appropriately investigated and resolved.



*Sixteen studies were papers which included a type 1 & type 2 diabetes population where separate analysis per diabetes type could not be obtained. The remaining 8 studies which were not included in meta-analysis, not enough information for meta-analysis was reported in the paper and could not provided by author when contacted.

**Three studies had a type 1 & type 2 diabetes population where separate analysis per diabetes type was obtained

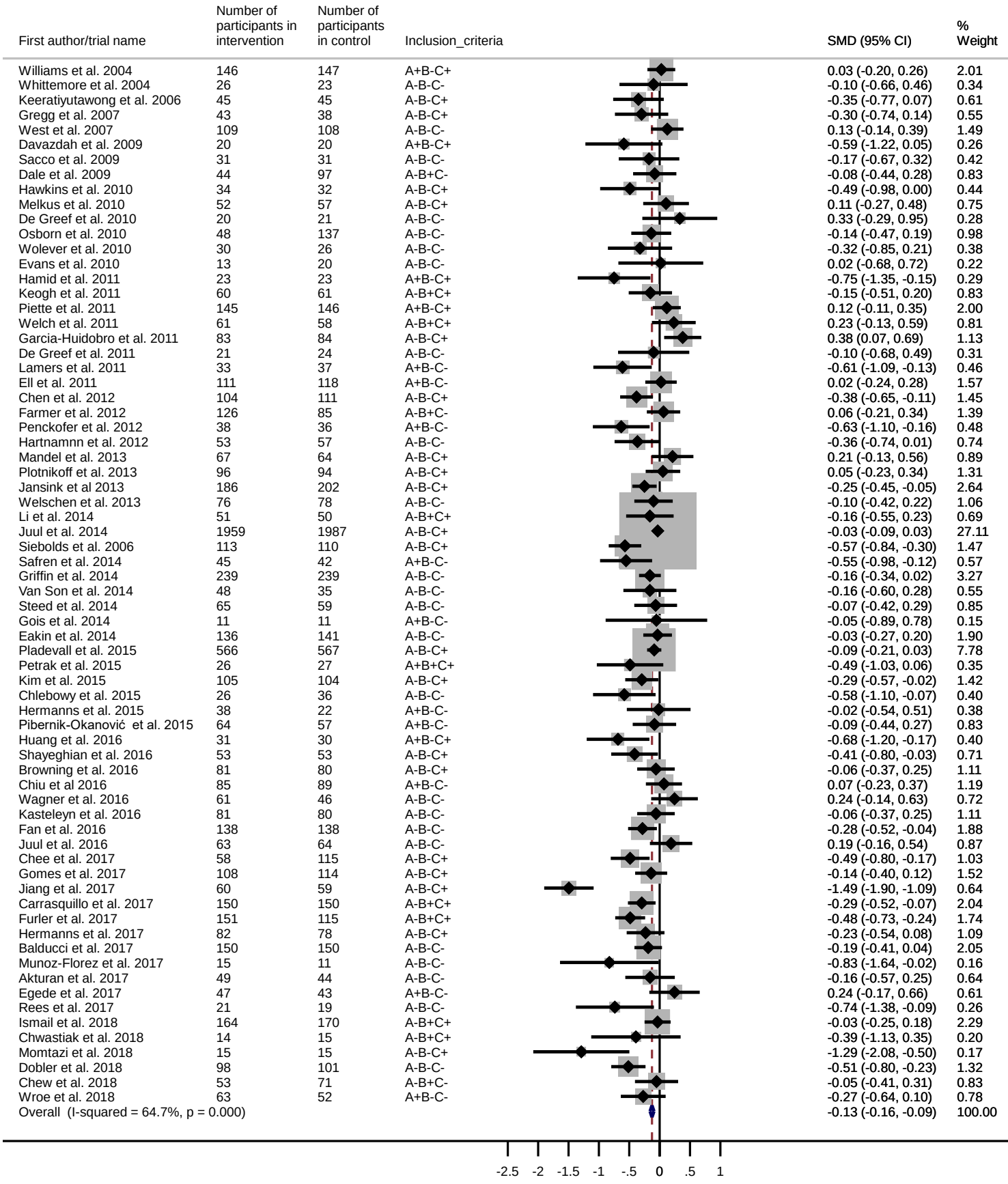


Figure 2 - Forest plot for a random-effect meta-analysis of standardised mean difference in HbA1c comparing psychological intervention versus with control group for adults with type 2 diabetes

A+=depressive symptoms in inclusion criteria, A-= depressive symptoms not inclusion criteria, B+= suboptimal HbA1c in inclusion criteria (7.5%/58mmol/mol or more), B-= suboptimal HbA1c not inclusion criteria, C+=HbA1c is primary outcome, C-=HbA1c is secondary outcome

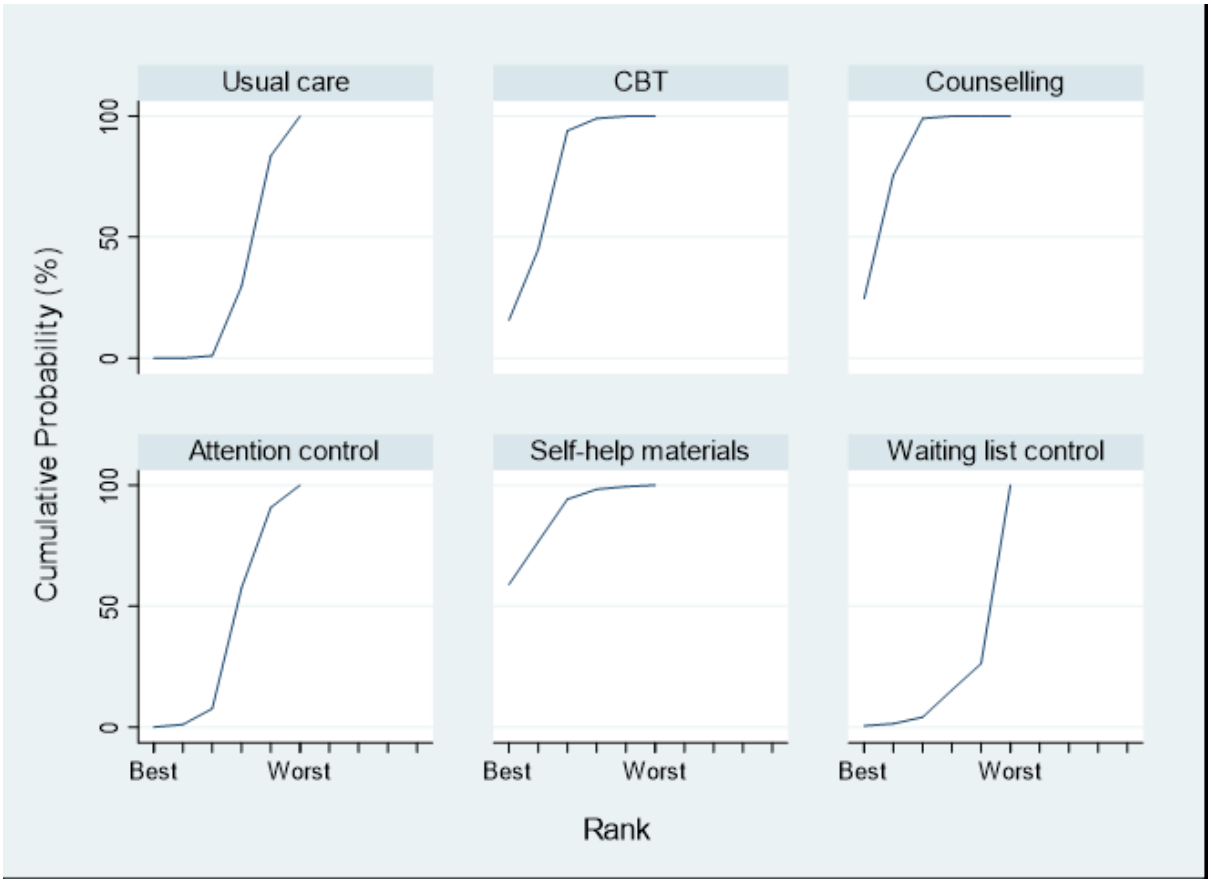


Figure 3 - Rankogram for all treatments. The plot shows the surface under the cumulative ranking curves for all treatments for adults with type 2 diabetes. For example, usual care has a very low probability to be among the best treatments but a very high to be one of the worst.

Table 1 - Study and intervention characteristics of RCTs

Year, Country, reference	Total number of participants	Type of psychological intervention	Number of sessions in intervention	Intervention Description (Intervention name, facilitator, format, individual/group)	Control Description (Control category, facilitator, format, individual/group)
Studies included in meta-analysis and systematic review					
2004, USA, Whittemore (Whittemore et al., 2004)	49	Counselling	6	Nurse-Coaching Intervention, Nurses, face-to-face, individual.	Usual care
2004, USA, Williams (Williams et al., 2004)	293	CBT	6-8	Collaborative care (depression treatment including problem solving treatment); depression clinical specialist + GP; face-to-face; individual	Usual care
2006, Germany, Siebolds (Siebolds et al., 2006)	223	Counselling	4	Counselling, Physician, face-to-face, individual.	Dietary counselling, Physician, face-to-face, individual.
2006, Thailand, Keeratiyutawong (Keeratiyutawong et al., 2006)	90	CBT	5	Self-management Group; Psychology researcher; face-to face; group	Diabetes education; Diabetes health care team; face-to-face; individual
2007, USA, Gregg (Gregg et al., 2007)	81	CBT	1	Acceptance and commitment therapy (ACT), Psychologist, face-to-face, group.	Diabetes education, psychology masters-level students, face-to-face, group.
2007, USA, West (West et al., 2007)	217	Counselling	5	Motivational interviewing; clinical psychologists; face-to-face; individual	Diabetes education; health educators; face-to-face; individual
2009, UK, Dale (Dale et al., 2009)	231	Counselling	6	1) Telephone support (motivational interviewing); nurses; telephone; individual 2) Telephone support (motivational interviewing); peers; telephone; individual	Usual care
2009, Iran, Davazdah (Davazdah Emamy et al., 2009)	40	CBT	12	CBT, trained researcher, face to face, Group	Waiting list; see intervention description
2009, USA, Sacco (Sacco, 2009)	62	Counselling	18	Telephone ‘‘coaching’’ intervention; Undergraduates in Psychology; telephone; individual	Usual care
2010, Australia, Evans (Evans, Lewin, et al., 2010)	60	CBT	7	CBT; face to face; group	Waiting list (usual care for 3 months then intervention)
2010, USA, Wolever (Wolever et al., 2010)	56	Counselling	14	Integrative health (IH) coaching; coaches (masters-level degrees in social work or psychology); telephone; individual	Usual care

2010, USA, Melkus (D'Eramo Melkus et al., 2010)	109	CBT	11	CBT+DSMT+CST; Nurse; face to face; group	Diabetes education; Nurse; face-to-face; group
2010, Belgium De Greef (De Greef et al., 2010)	41	CBT	5	Cognitive-behavioural pedometer-based group intervention; coaches (degree in PE, movement sciences or clinical psychology); face to face; group	Usual care
2010, USA, Hawkins (Hawkins, 2010)	66	Counselling	12	Motivational interviewing video call; nurses, telephone, individual	Attention control telephone support (no MI); nurses; telephone; individual
2010, USA, Osborn (Osborn et al., 2010a)	185	Counselling	1	Culturally tailored diabetes self-care intervention; bilingual medical assistant of Puerto Rican heritage; face to face; individual	Usual care
2011, Chile, Garcia-Huidobro (Garcia-Huidobro et al., 2011)	167	Counselling	4	Family intervention, Healthcare team, face-to-face, family	Usual care
2011, Ireland, Keogh (Keogh et al., 2011)	121	Counselling	3	Family-based intervention; Health psychologist; face to face; family	Usual care
2011, Belgium, De Greef (De Greef et al., 2011)	67	Counselling	3	1) Group behavioural intervention; clinical psychologist; face to face; group 2) individual consultation; GP, face to face, individual	Usual care
2011, Iran, Hamid (Hamid, 2011)	46	CBT	12	CBT, trained researcher, face to face, Group	Waiting list, see intervention description
2011, USA, Piette (Piette et al., 2011)	291	CBT	12	Telephone delivered CBT; Nurses; telephone; individual	Enhanced usual care (usual care + copy of self-help book based on CBT for depression)
2011, Netherlands, Lamers (Lamers et al., 2011)	70	CBT	4	Minimal psychological intervention; Nurses; face to face; individual	Usual care
2011, USA, Welch (Welch et al., 2011)	119	Counselling	4	1) MI +Computerized self-management: Diabetes educator; face to face; individual 2) MI alone; Diabetes educator; face to face; individual	1) Diabetes education alone; diabetes educator; face to face; individual 2) Computer self-management alone; computer; individual
2011, USA, Ell (Ell et al., 2011)	229	CBT	Not reported	Sociocultural adapted collaborative care (relapse prevention): primary care physicians/graduate social workers/ diabetes depression clinical specialists (DDCS); face to face/telephone; individual	Enhanced usual care (usual care + prescribed antidepressant medication and provided counselling or refer to community mental health care.)
2012, UK, Farmer (Farmer et al., 2012)	211	Counselling	1	Consultation-based intervention, Clinical nurses, face-to-face, individual.	Usual care
2012, USA, Penckofer (Penckofer et al., 2012)	74	CBT	8	Psychoeducation: Nurses; face to face, group	Usual care

2012, Germany, Hartmann (Hartmann et al., 2012)	110	Counselling	8	Mindfulness-based intervention: psychologist and a resident in internal medicine; face to face; group	Usual care
2012, Taiwan, Chen (Chen, Creedy, et al., 2012)	215	Counselling	Not reported	Motivational interviewing: Nurses; face to face; individual	Diabetes Education; nurse/diabetes educator; face to face; group
2013, Canada, Plotnikoff (Plotnikoff et al., 2013)	287	Counselling	22	Telephone counselling (MI): five individuals with relevant degree qualifications related to PA promotion and/or counselling; telephone; individual	1) Diabetes education; Educational materials 2) Printed materials (relates to transtheoretical model)
2013, Netherlands, Welschen (Welschen et al., 2013)	154	CBT	3-6	CBT; diabetes nurse and dietician; face to face; individual	Usual care; dietician/diabetes nurse; face to face; individual
2013, USA, Mandel (Mandel et al., 2013)	131	CBT	4	Music therapy (relaxation and imagery); Music therapy clinician; face to face; group	1) Diabetes education; diabetes educator/dietician; face to face; group 2) music relaxation CD
2013, Netherlands, Jansink (Jansink et al., 2013)	521	Counselling	5-8	Motivational interviewing; Nurse; face-to-face; individual	Usual care
2014, Denmark, Juul (Juul, Maindal, Zoffmann, Frydenberg, & Sandbaek, 2014b)	3946	Counselling	Variable	Nurse-led diabetes consultations, GP & nurses, face-to-face, individual.	Usual care
2014, UK, Steed (Steed et al., 2014)	124	Counselling	5	Self-management intervention, Diabetes specialist nurse & dietician, face-to-face, group.	Usual care
2014, USA, Safren (Safren et al., 2014)	87	CBT	9-12	CBT-AD: Therapist; face to face; individual	Enhanced usual care; nurse/dietician; face to face; individual
2014, Portugal, Gois (Gois et al., 2014)	22	Interpersonal Psychotherapy (IPT)	12	Interpersonal Psychotherapy (IPT), Psychiatry, face-to-face, individual.	Medical care & sertraline
2014, China, Li (Li et al., 2014)	101	Counselling	4	Motivational interviewing; therapist; face to face; individual	Diabetes Education; face to face; individual
2014, UK, Griffin (Griffin et al., 2014)	478	Counselling	8	Intensive plus behavioural intervention: Life-style facilitators; face to face/telephone; individual	Enhanced usual care; GP; face to face; individual
2014, Australia, Eakin (Eakin et al., 2014)	277	Counselling	27	Telephone counselling (MI): trained researchers (degree nutrition or dietetics); telephone; individual	Usual care
2014, Netherlands, van Son (van Son, Nyklíček, et al., 2014)	83	CBT	8	Mindfulness cognitive based therapy; psychologist; face to face; group	Usual care

2015, USA, Kim (Kim et al., 2015b)	209	Counselling	6	Self-management intervention, Nurses & community health workers, face-to-face, group.	Diabetes education, face-to-face, group.
2015, USA, Chlebowy (Chlebowy et al., 2015)	62	Counselling	4	Motivational interviewing: Nurses; face to face; individual	Usual care
2015, USA, Pladevall (Pladevall et al., 2015)	1692	Counselling	6	Motivational interviewing and adherence information: Nurses and pharmacists; face to face/telephone; individual	1) Usual care 2) Adherence information; clinicians; face to face; individual
2015, Germany, Hermanns (Hermanns et al., 2015a)	60	CBT	5	DIAMOS: Psychologists, face to face; group	Diabetes Education; diabetes educators; face to face; group
2015, Croatia, Pibernik-Okanović (Pibernik-Okanović, 2015)	121	CBT	6	Psychoeducation: Psychologist; Face to face; Group	Diabetes Education; diabetologist; face to face; group
2015, Germany, Petrak (Petrak, 2015)	53	CBT	10	CBT, Clinical psychologists, face-to-face, group	Usual care and antidepressants
2016, Taiwan, Huang (Huang et al., 2016)	61	CBT	12	MET+CBT: Psychotherapist/clinical nurse; face to face; Group	Usual care
2016, China, Browning (Browning et al., 2016)	682	Counselling	9	Health coaching: Clinicians (doctors, nurses and psychologists; face-to-face/telephone; individual	Usual care
2016, Netherlands, Kasteleyn (Kasteleyn, 2016)	161	Counselling	3	Motivational interviewing: Nurses; face to face; individual	Less intensive psychological intervention; nurse, telephone; individual
2016, Taiwan, Chiu (Chiu et al., 2016)	174	Counselling	4	Minimal Psychological Intervention: Psychology assistants; telephone; individual	Usual care
2016, China, Fan(Fan et al., 2016)	276	Counselling	3	Individualized diabetes education; Nurses and clinical psychologists; face to face; group	Diabetes education; nurses; face to face; group
2016, Denmark, Juul(Juul et al., 2016)	127	Counselling	6	Health promotion intervention; Dietician, occupational therapist; face to face; group	Waiting list control
2016, Iran, Shayeghian(Shayeghian et al., 2016)	106	CBT	10	ACT; Clinical psychologists; face to face; group	Waiting list control
2016, USA, Wagner(Wagner et al., 2016)	107	Counselling	8	Stress management intervention; Community health worker; face to face; individual	Diabetes education; Community health worker; face to face; individual

2017, Turkey, Akturan(Akturan et al., 2017)	93	Counselling	3	BATHE interview technique; Physicians; face to face; individual	Usual care
2017, Italy, Balducci(Balducci et al., 2017)	300	Counselling	9	Counselling; Diabetologists and exercise specialists; face to face; individual	Usual care
2017, Malaysia, Chee(Chee et al., 2017)	230	Counselling	1	1) Trans-cultural motivational interviewing; Dietician and physician; face to face; individual 2) Trans-cultural counselling; Dietician and physician; face to face; individual	Usual care
2017, USA, Egede(Egede et al., 2018)	90	CBT	8	Behaviour activation treatment; therapists; face to face; individual	Behaviour activation treatment; therapists; face to face; video teleconferencing
2017, Australia, Furler(Furler et al., 2017)	266	Counselling	Variable	The Stepping Up model of care intervention; nurses; face to face; individual	Usual care
2017, Germany, Hermanns(Hermanns et al., 2017)	160	Counselling	6	Self-management-oriented education programme; Diabetes educators; face to face; group	Diabetes education; diabetes educators; face to face; group
2017, Spain, Munoz-Florez(Muñoz-Flórez & Cortés, 2017)	26	Counselling	Variable	Motivational interviewing; Psychologist; face to face; individual	Educational materials and usual care
2017, Australia, Rees(Rees et al., 2017)	40	CBT	8	Problem-solving therapy; Research assistant trained in PST supervised by clinical psychologist; telephone and face to face; individual	Usual care
2017, USA, Carrasquillo(Carrasquillo et al., 2017)	300	Counselling	Variable	Community Health Worker Intervention; Community health workers; telephone & face to face; individual	Enhanced usual care (usual care +education materials)
2017, Brazil, Gomes(Gomes et al., 2017)	222	Counselling	4	Family social support; families; telephone; family	Education; telephone; individual
2017, China Jiang(Jiang et al., 2017)	52	Counselling	Not reported	Problem-solving treatment, face-to-face, group	Usual care plus paroxetine
2018, Malaysia, Chew(Chew et al., 2018)	124	Counselling	4	VEMOFIT (emotion focused education programme); Nurse and physician; face to face; group	Attention control; Nurse and physician; face to face; group

2018, USA, Chwastiak(Chwastiak et al., 2017)	29	Counselling	12	Collaborative care; Nurse case manager, psychiatrist, advanced practice nurse; face to face; individual	Usual care
2018, Germany, Dobler(Döbler et al., 2018)	199	Counselling	12	Telephone support group; Counsellors; face to face; individual	Usual care
2018, UK, Ismail (Ismail et al., 2018)	334	Counselling	12	D6 (MI+CBT); nurses; face to face; individual	Usual care
2018, Iran, Momtzi(Momtazi et al., 2018)	30	Counselling	4	Motivational interviewing; Psychiatrist; face to face; group	Waiting list control
2018, UK, Wroe(Wroe et al., 2018)	115	CBT	6	Wellbeing Group; IAPT practitioners; face to face; group	Usual care
				Studies included in systematic review only	
2004, UK, Clark (Clark, Hampson, Avery, & Simpson, 2004)	100	Counselling	1	Self-management intervention: Interventionist (trained in MI); face to face; individual	Usual care
2004, Norway, Karlsen (Karlsen, Idsoe, Dirdal, Rokne Hanestad, & Bru, 2004)	63	CBT	9	Group-based counselling; nurse; face to face; group	Waiting list
2006, USA, Hokanson (Hokanson, Anderson, Hennrikus, Lando, & Kendall, 2006)	114	Counselling	4-7	Smoking cessation motivational interviewing, research staff, telephone, individual	Usual care
2010, The Netherlands, Heinrich (Heinrich, Candel, Schaper, & de Vries, 2010)	537	Counselling	8	Motivational interviewing; nurses; face to face; individual	Usual care
2010, Iran, Pourisharif (Pourisharif et al., 2010)	41	Counselling	4	1) Motivational interviewing; face to face; group 2) CBT; face to face; group	Usual care

2011, Italy, Castelnuovo (Castelnuovo et al., 2011)	34	CBT	Variable	TECNOB (TEChnology for OBesity): Clinical psychologist; Face to face/telephone/ online and text messaging; individual/ group	Usual care
2012, USA, Waker (Waker, 2012)	154	Counselling	2	Motivational interviewing: researcher; face to face; individual	Usual care
2013, USA, Gabbay (Gabbay et al., 2013)	545	Counselling	8	Motivational interviewing: Nurses; face to face; individual	Usual care
2015, USA, Inouye (Inouye, Li, Davis, & Arakaki, 2015)	207	CBT	6	CBT: Research assistants; face to face; Group	Diabetes education; research assistants; face to face; group
2016, USA, Fitzpatrick (Fitzpatrick, 2016)	182	Counselling	9	1) DECIDE Group, graduate assistant, face-to face, group 2) DECIDE individual, graduate assistant, face-to face, individual	1) Enhance usual care (usual care + education materials), face-to-face/mail, individual 2) DECIDE self-study; mail; individual
2016, Netherlands, Rondags(Rondags, de Wit, Twisk, & Snoek, 2016)	14	Counselling	3	Blood glucose awareness training; diabetes professionals; face-to-face; group	Usual care
2017, Canada, Cummings(Cummings et al., 2017)	129	CBT	16	Lifestyle coaching; Peers; face to face; telephone	Usual care
2017, USA, Egede(Egede et al., 2017)	255	Counselling	12	Telephone-Delivered Behavioural Skills Intervention (knowledge, skills, or knowledge & skills); health educators; telephone; individual	Usual care
2017, New Zealand. Friis(Friis, Johnson, Cutfield, & Consedine, 2016)	17	Counselling	8	Mindful self-compassion (MSC) intervention; health psychologists; face-to-face; group	Waiting list
2017, Finland, Tovote(Tovote et al., 2017)	56	CBT	8	Mindfulness-Based Cognitive Therapy; CBT therapists; face to face; individual	Waiting list
2017, New Zealand, Whitehead(Whitehead et al., 2017)	97	CBT	1	Education + ACT; clinical psychologist & nurses; face to face; group	1) Diabetes education; nurses; face to face; group 2) Usual care

2018, Netherlands, Berk(Berk et al., 2018)	158	CBT	14	Group cognitive behavioural therapy; trained psychologist/psychotherapist, with experience in diabetes care; face to face; group	Usual care
2018, Iran, Kian(Armani Kian et al., 2018)	59	Counselling	8	Mindfulness-Based Stress Reduction; Mindfulness instructor; face to face; group	Usual care
2018, USA, Pyatak(Pyatak et al., 2018)	19	Counselling	Variable	Occupational therapy; occupational therapists; face to face; individual	Attention control follow-up phone calls
2014, USA, Lin (Lin et al., 2014)	Not reported	Counselling	Variable	Collaborative care; Primary care physician & nurse & psychiatrist & psychologist; face to face; individual	Usual care
2011, Denmark, Minet (Minet, Wagner, Lonvig, Hjelmborg, & Henriksen, 2011)	349	Counselling	5	Motivational interviewing; HCPs (nurse, dietician, physiotherapist or psychologist); face to face; individual	Usual care
2015, USA, Safford (Safford et al., 2015)	Not reported	Counselling	Variable	Motivational interviewing; peers, telephone; individual	Diabetes education; face to face; individual
2015, Netherlands, Schroevers (Schroevers et al., 2015)	24	CBT	8	Mindfulness-based cognitive therapy (MBCT); clinical psychologist; face to face; individual	Waiting list
2011, USA, Weinger (Weinger et al., 2011)	222	CBT	5	Structured behavioural group; diabetes educators; face to face, group	1) Group attention control; diabetes educators; face to face, group 2) Individual control; diabetes educators; face to face; individual

Appendix 2.1.1. Supplementary material: Psychological interventions to improve glycaemic control in type 2 diabetes: a systematic review and meta-analysis.

Table S1 – Search strategy for the systematic review of psychological interventions for people with Type 2 diabetes

1. exp Diabetes Mellitus/
2. diabet$.ab,ti.
3. (DKA or IDDM).mp. or DMI.ab,ti. [mp=title, original title, abstract, name of substance word, subject heading word]
4. (MODY or DM2 or NIDDM).mp. or IIDM.ti,ab. [mp=title, original title, abstract, name of substance word, subject heading word]
5. insulin$ secret$ dysfunc$.ti,ab.
6. insulin$ resist$.ti,ab.
7. ((impaired glucose tolerance or glucose intoleran$ or insulin$ resist$) and (DM or DM2)).ti,ab.
8. insulin$ depend$.mp. or insulin?depend$.ti,ab. [mp=title, original title, abstract, name of substance word, subject heading word]
9. (non insulin$ depend$ or nonisulin$ depend$ or nonisulin?depend).mp. or non insulin?depend$.ti,ab. [mp=title, original title, abstract, name of substance word, subject heading word]
10. (("typ$ 1" or typ$ I) adj6 DM).ti,ab.
11. (("typ$ 2" or typ$ II) adj6 DM).ti,ab.
12. ((juvenil$ or child$ or keto$ or labil$ or brittl$ or earl$ onset) adj6 (DM or DM1)).ti,ab.
13. ((keto$ prone or autoimmun$ or auto immun$ or sudden onset) adj6 (DM or DM1)).ti,ab.
14. ((keto$ resist$ or nonketo$ or non keto$ or adult$ onset or matur$ onset or late$ onset or slow onset or stabl$) adj6 (DM or DM2)).ti,ab.
15. exp Insulin Resistance/
16. (insulin$ defic$ adj6 (absolut$ or relativ$)).ti,ab.
17. metabolic$ syndrom$.ti,ab.
18. (syndrom$ X not (fragil$ X or X linked)).ti,ab.
19. (plurimetabolic$ syndrom$ or pluri metabolic$ syndrom$).ti,ab.
20. or/1-19
21. exp Psychotherapy/
22. exp Counseling/
23. exp Mood disorders/
24. exp Depression/
25. psycho$.mp
26. counsel$.mp
27. depression.mp
28. depressive.mp
29. (interpersonal adj5 therap$).mp
30. art therap$.mp
31. aversion therap$.mp
32. balint.mp
33. behavio?r adj5 (intervention or therap* or modific*)
34. cognitive adj5 (therap* or intervention or program* or train* or theory)
35. (family adj3 (intervention or treatment or counsel* or therap*)

36. colo?r therap$.mp.
37. crisis intervention.mp
38. dance therap$.mp
39. gestalt therap$.mp
40. music therap$.mp
41. milieu therap$.mp
42. (assert$ adj5 training).mp
43. Narrative therap$.mp.
44. nondirective therap$.mp
45. (problem solving adj5 therap$).mp
46. (self control adj5 therap$).mp
47. person cent$.mp
48. client cent$.mp
49. psychodrama$.mp
50. paradoxical technique$.mp
51. play therap$.mp
52. rational emotive.mp
53. reality therap$.mp
54. role play$.mp
55. (relax$ adj5 training).mp
56. sociotherap$.mp
57. socioenvironmental.mp
58. supportive therap$.mp
59. transactional.mp
60. acceptance adj2 (commitment therap*)
61. coping skills training.mp.
62. exp Mindfulness/
63. motivation* adj2 (interview* or therap*)
64. multisystemic therapy
65. or/21-64
66. Randomized Controlled Trials as Topic/
67. randomized controlled trial/
68. Random Allocation/
69. Double Blind Method/
70. Single Blind Method/
71. clinical trial/
72. clinical trial, phase i.pt
73. clinical trial, phase ii.pt
74. clinical trial, phase iii.pt
75. clinical trial, phase iv.pt
76. controlled clinical trial.pt
77. randomized controlled trial.pt
78. multicenter study.pt
79. clinical trial.pt
80. exp Clinical Trials as topic/
81. (clinical adj25 trial$).tw
82. ((singl$ or doubl$ or treb$ or tripl$) adj25 (blind$3 or mask$3)).tw
83. PLACEBOS/
84. placebo$.tw
85. randomly allocated.tw
86. (allocated adj2 random$).tw

87. Or/66-86
88. case report.tw
89. letter/
90. historical article/
91. Or/ 88-90
92. 87 NOT 91
93. 20 AND 65 AND 92
94. limit 88 to yr="2003 -Current"

Table S2 – Case definition of included meta-analysed studies

Year, Country, reference	Mean age (SD or range), years intervention group	Mean age (SD or range), years control group	Mean (SD or range) duration of diabetes, years intervention group	Mean (SD or range) duration of diabetes, years control group	Mean (SD) baseline HbA1c intervention group	Mean (SD) baseline HbA1c control group	Age inclusion criteria (years)	Diabetes duration inclusion criteria (months)	HbA1c inclusion criteria
2004, USA, Whittemore (Whittemore et al., 2004)	All: 57·6 (10·9)	All: 57·6 (10·9)	All: 2·7 (3·0)	All: 2·7 (3·0)	7.7% (1.00)	7.6% (1.00)	30-70	None	7% or more
2004, USA, Williams (Williams et al., 2004)	70·1 (6·9)	70·3 (7·1)	NR	NR	7.26% (1.32)	7.30% (1.43)	≥60	None	None
2006, Germany, Siebolds (Siebolds et al., 2006)	58·7 (7·6)	60·5 (6·6)	65·5 (57·2)	62·6 (47·3)	8.47% (0.86)	8.35% (0.75)	≥18	None	None
2006, Thailand, Keeratiyutawong (Keeratiyutawong et al., 2006)	NR	NR	NR	NR	8.93% (2.4)	7.89% (1.8)	21-60	<120	None
2007, USA, Gregg (Gregg et al., 2007)	49·8	49.8	5·3	6·6	8.17% (1.86)	8.21% (1.91)	≥18	None	None
2007, USA, West (West et al., 2007)	54.0 (10.0)	52.0 (10.0)	5·8 (6·5)	4·9 (5.0)	7.54% (1.4)	7.62% (1.4)	≥18	None	None
2009, UK, Dale (Dale et al., 2009)	NR	NR	NR	NR	1) 8.9% (1.5) 2) 8.4% (1.1)	8.7% (1.3)	≥18	None	>7.4%
2009, Iran, Davazdah (Davazdah Emamy et al., 2009)	NR	NR	NR	NR	7.04% (1.39)	7.51% (1.53)	≥18	None	None
2009, USA, Sacco (Sacco, 2009)	All: 52(8·6)	All: 52(8·6)	All: 9·5 (7·2)	All: 9·5 (7·2)	8.4% (1.37)	8.5% (2.01)	18-65	None	None
2010, Australia, Evans (Evans, Lewin, et al., 2010)	All: 57·1(22-84)	All: 57·1(22-84)	All: 14·3(1-45)	All: 14·3(1-45)	8.33% (1.44)	7.41 (1.64)	≥18	None	None
2010, USA, Wolever (Wolever et al., 2010)	53·1 (8·29)	52·8(7·64)	11·8 (8·5)	10·6 (6·43)	7.7% (1.94)	8.2% (1.89)	≥18	≥12	None

2010, USA, Melkus (D'Eramo Melkus et al., 2010)	47.0 (9.0)	45.0 (10.0)	NR	NR	8.0% (2.1)	8.3% (2.2)	21-65	None	None
2010, Belgium De Greef (De Greef et al., 2010)	NR	NR	NR	NR	7.5% (1.1)	8.0% (1.3)	35-75	≥6	None
2010, USA, Hawkins (Hawkins, 2010)	64	65·8 (10·4)	NR	NR	9.0% (2.3)	8.9% (3.1)	≥60	None	7% or more
2010, USA, Osborn (Osborn et al., 2010a)	56·9 (11·3)	58·4 (10·1)	13·2 (12)	12·3 (9·4)	7.8% (1.4)	7.3% (1.6)	≥18	≥12	None
2011, Chile, Garcia-Huidobro (Garcia-Huidobro et al., 2011)	53·4 (8·1)	53·5 (9·8)	NR	NR	10.3% (2.0)	9.5% (2.2)	18-70	None	7% or more
2011, Ireland, Keogh (Keogh et al., 2011)	59·96 (11·67)	57·29 (11·34)	9·17(7·1)	9·65 (6·45)	Median: 9.06 (0.96)	Median: 9.29 (1.13)	>18	>12	8% or more
2011, Belgium, De Greef (De Greef et al., 2011)	I1: 70 (6·3) I2: 66·6 (9·5)	66 (11·1)	NR	NR	I1: 7.23% (0.71) I2: 7.12% (1.35)	7.0 (0.87)	<80	≥6	<12%
2011, Iran, Hamid (Hamid, 2011)	NR	NR	NR	NR	9.03% (3.1)	9.1% (3.6)	≥18	None	None
2011, USA, Piette (Piette et al., 2011)	55·1 (9·4)	56 (10·9)	NR	NR	7.5% (1.7)	7.7% (1.7)	≥21	None	None
2011, Netherlands, Lamers (Lamers et al., 2011)	70·7 (6·6)	69·7 (6·6)	8·2 (8·8)	9·8 (9·1)	7.5% (1.1)	7.2% (1.4)	≥60	None	None
2011, USA, Welch (Welch et al., 2011)	I1: 56·1 (10·4) I2: 54·9 (9·3)	C1: 57·2 (10·9) C2: 54·4 (10·3)	I1: 9·8 (8) I2: 9 (7·3)	C1: 7 (6·5) C2: 7·1 (5·8)	I1: 9.1 (1.5) I2: 8.8 (1.0)	C1: 8.8 (1.3) C2: 8.9 (1.2)	30-70	None	7.5% or more
2011, USA, Ell (Ell et al., 2011)	All: 54 (8·7)	All: 54 (8·7)	NR	NR	9.03% (2.23)	9.13% (2.21)	≥18	None	None
2012, UK, Farmer (Farmer et al., 2012)	62·5 (11.0)	64·1 (10·3)	6·7 (4·8)	6·9 (5·3)	8.37% (1.25)	8.28% (1.22)	≥18	≥3	7.5% or more

2012, USA, Penckofer (Penckofer et al., 2012)	54·8 (8·8)	54 (8·4)	10·5 (8·2)	10 (6·5)	7.8% (1.8)	7.9% (2.0)	≥18	≥6	None
2012, Germany, Hartmann (Hartmann et al., 2012)	58·7 (7·4)	59·3 (7·8)	11.0 (7·5)	12·2 (7·6)	7.26% (1.08)	7.27% (1.06)	30-70	<36	None
2012, Taiwan, Chen (Chen, Creedy, et al., 2012)	59·19 (10·24)	58·67 (10·23)	7·98 (7·57)	7·91 (6·95)	8.92% (2.17)	8.52% (1.82)	>18	>3	None
2013, Canada, Plotnikoff (Plotnikoff et al., 2013)	62·3 (11·1)	C1: 61.0 (11·7) C2: 61·4 (12·6)	8·8 (7.0)	C1: 11·7 (9·9) C2: 10·7 (9·9)	7.08% (1.3)	C1: 7.06% (1.9) C2: 7.24% (0.12)	≥18	None	None
2013, Netherlands, Welschen (Welschen et al., 2013)	60·5 (9·4)	61·2 (8·8)	7·6 (5)	7·8 (6·1)	6.8% (1.0)	6.7% (1.0)	18-75	None	7% or more
2013, USA, Mandel (Mandel et al., 2013)	58 (11·29)	C1: 57·1 (9·67) C2: 58·9 (10·76)	3·22 (5·94)	C1: 2·32 (6·1) C2: 3·78 (7·06)	7.7% (1.81)	C1: 7.4% (1.56) C2: 7.6% (1.48)	30-85	None	None
2013, Netherlands, Jansink (Jansink et al., 2013)	64·1 (8·9)	63·9 (9·8)	7·5 (6·0)	7·8 (5·8)	7.8% (0.9)	7.7% (0.7)	<80	None	7% or more
2014, Denmark, Juul (Juul et al., 2014b)	60·2 (8·2)	60·7 (8·6)	8 (4-14)	8 (4-15)	7.1% (1.3)	7.1% (1.3)	40-74	None	None
2014, UK, Steed (Steed et al., 2014)	59·2 (8·8)	60·3 (8·6)	10·7 (7·5)	10·9 (7·9)	8.2% (1.3)	8.6% (1.8)	< 75	None	None
2014, USA, Safren (Safren et al., 2014)	55·44 (8·72)	58·31 (7·41)	NR	NR	8.81% (1.78)	8.74% (1.41)	18-70	None	7% or more
2014, Portugal, Gois (Gois et al., 2014)	56·82 (4·25)	53·81 (7·04)	13·12 (4·85)	11·63 (6·68)	9.36% (2.38)	8.76% (1.94)	18-65	>6	None
2014, China, Li (Li et al., 2014)	58·5 (5.0)	59·2 (5·2)	1·3 (0·5)	1·2 (0·4)	10.1% (2.7)	9.7% (3.5)	40-70	12-24	9% or more

2014, UK, Griffin (Griffin et al., 2014)	59·5 (7·5)	59·8 (7·5)	NR	NR	7.23% (1.62)	7.01% (1.23)	40-69	< 36	None
2014, Australia, Eakin (Eakin et al., 2014)	57·7 (8·1)	58·3 (9·0)	NR	NR	Median: 7.6% (6.3, 8.5)	Median: 7.0% (6.4, 7.9)	20-75	None	None
2014, Netherlands, van Son (van Son, Nyklíček, et al., 2014)	56.0 (13.0)	57.0 (13.0)	NR	NR	7.5% (1.2)	7.6% (1.2)	18-80	None	None
2015, USA, Kim (Kim et al., 2015b)	59·1 (8·4)	58·3 (8·5)	In months: 105·3 (87·6)	In months: 99·3 (84·8)	8.9% (2.05)	8.8% (3.06)	≥35	None	7% or more
2015, USA, Chlebowy (Chlebowy et al., 2015)	55·8 (2·1)	53 (2·25)	NR	NR	7.8% (0.16)	8.1% (0.18)	≥18	None	None
2015, USA, Pladevall (Pladevall et al., 2015)	64·5 (10·5)	C1: 64·9 (11·5) C2: 63·3 (10·9)	NR	NR	8.0% (1.3)	C1: 8.2% (1.4) C2: 8.0% (1.4)	≥18	None	7% or more
2015, Germany, Hermanns (Hermanns et al., 2015a)	34·2 (14·9)	43·4 (13·8)	14·2 (10·3)	14·2 (10·7)	8.9% (1.8)	8.9% (1.8)	18-70	None	None
2015, Croatia, Pibernik-Okanović (Pibernik-Okanović, 2015)	57·7 (6·2)	58·2 (5·6)	11·4 (9·1)	10·5 (6·9)	7.4% (1.2)	7.2% (1.1)	18-65	≥12	None
2015, Germany, Petrak (Petrak, 2015)	49 (10·6)	47·9 (12·8)	15·7 (10·4)	15·0 (10·6)	9.30% (1.49)	9.20% (1.44)	21-69	None	7.5% or more
2016, Taiwan, Huang (Huang et al., 2016)	55·06 (10·44)	57·83 (10·38)	In months: 44·32 (21·59)	In months: 45·7 (18·06)	7.68% (1.44)	7.84% (1.95)	≥20	None	None
2016, China, Browning (Browning et al., 2016)	63·7 (7·6)	64.0 (9.0)	10.0 (6·5)	9·6 (6·6)	10.60% (2.09)	10.29% (1.71)	≥50	None	None
2016, Netherlands, Kasteleyn (Kasteleyn, 2016)	66.0 (9·3)	65·6 (9·4)	7.0 (2·8-16)	8·5 (5-15)	7.2% (3.5)	6.8% (3.1)	>35	>12	None

2016, Taiwan, Chiu (Chiu et al., 2016)	64·78 (0·3)	64·59 (0·4)	10.0 (0·6)	10·58 (0·2)	7.6% (1.5)	7.7% (1.3)	≥50	None	None
2016, China, Fan(Fan et al., 2016)	62·94 (10·72)	64·89 (10·14)	11·4 (4·8)	11·6 (5·0)	9.61% (1.92)	9.80% (1.98)	None	None	None
2016, Denmark, Juul(Juul et al., 2016)	Median: 58 (50, 63)	Median: 60 (51, 64)	NR	NR	40.7 mmol/mol (3.5)	40.6 mmol/mol (3.9)	<70	None	6-6.4%
2016, Iran, Shayeghian(Shayeghian et al., 2016)	55·18 (8·26)	55·70 (8·98)	4·9 (1·40)	4·54 (1·54)	7.46% (1.66)	7.61% (1.38)	40-60	12-120	None
2016, USA, Wagner(Wagner et al., 2016)	60.0 (11·2)	60·8 (12·1)	NR	NR	8.5% (1.4)	8.6% (1.9)	≥18	≥6	7% or more
2017, Turkey, Akturan(Akturan et al., 2017)	57·51 (7.0)	56·33 (7·56)	NR	NR	7.48% (1.49)	7.39% (1.28)	18-80	≥6	None
2017, Italy, Balducci(Balducci et al., 2017)	NR	NR	NR	NR	7.43% (1.60)	7.32% (1.37)	40-80	≥12	None
2017, Malaysia, Chee(Chee et al., 2017)	NR	NR	NR	NR	I1: 7.7% (1.1) I2: 7.7% (1.4)	7.9% (1.3)	30-65	None	7-11%
2017, USA, Egede(Egede et al., 2018)	62·7 (3·4)	63·5 (4·9)	NR	NR	7.35%	6.90%	≥58	None	None
2017, Australia, Furler(Furler et al., 2017)	61·7 (9·7)	62·0 (10·6)	NR	NR	8.7% (8.1-9.7)	8.5% (8-9.6)	<80	None	7.5% or more
2017, Germany, Hermanns(Hermanns et al., 2017)	NR	NR	NR	NR	8.0% (1.3)	7.9% (1.2)	18-75	None	None
2017, Spain, Munoz-Florez(Muñoz-Flórez & Cortés, 2017)	66.0 (9·45)	63.0 (12·82)	NR	NR	156.3 mg/DL (47.79)	134 mg/DL (46.6)	≥20	None	None
2017, Australia, Rees(Rees et al., 2017)	60·1 (7.0)	58·6 (8·8)	17·5 (10)	23.0 (15.0)	8.2% (1.57)	8.1% (1.2)	None	None	None
2017, USA, Carrasquillo	55·3 (7·1)	55·2 (6·1)	11·7 (8·2)	11·2 (8·4)	9.3% (2.1)	9.3% (1.9)	18-65	≥6	8% or more

2017, Brazil, Gomes(Gomes et al., 2017)	NR	NR	NR	NR	9.47% (2.01)	9.40% (2.00)	≥40	None	None
2017, China Jiang(Jiang et al., 2017)	56·3 (5·3)	57·1 (5·5)	1·24 (0·38)	1·27 (0·36)	7.7% (0.9)	8.3% (1.1)	18-70	None	None
2018, Malaysia, Chew(Chew et al., 2018)	55·6 (10·8)	55·8 (8·8)	NR	NR	9.9% (1.8)	9.5% (2.1)	≥18	≥24	8% or more
2018, USA, Chwastiak(Chwastiak et al., 2017)	NR	NR	NR	NR	9.4% (2.2)	8.3% (1.9)	18-64	≥6	8% or more
2018, Germany, Dobler(Döbler et al., 2018)	51·6 (5·7)	52·2 (5·4)	8·7 (6·6)	9·6 (5·9)	7.8% (1.7)	7.6% (1.4)	18-70	None	None
2018, UK, Ismail (Ismail et al., 2018)	59 (11·1)	58·9 (11·4)	10.0 (7-13)	9.0 (5-12)	81.0 mmol/mol (17.1)	80.1 mmol/mol (19.1)	18-79	≥24	8% or more
2018, Iran, Momtzi(Momtazi et al., 2018)	NR	NR	NR	NR	8.23% (1.10)	7.98% (0.80)	30-60	None	7% or more
2018, UK, Wroe(Wroe et al., 2018)	63·48 (11·04)	63·63 (10·71)	NR	NR	67.12 mmol/mol (21.02)	61.86 mmol/mol (14.29)	None	None	None

Table S3 – Primary outcome of included meta-analysed studies

Reference	Primary outcome category	Primary outcome description
Whittemore et al. 2004	Self-management	Diet self-management
Williams et al. 2004	HbA1c	HbA1c
Keeratiyutawong et al. 2006	HbA1c	HbA1c
Gregg et al. 2007	HbA1c	HbA1c
West et al. 2007	Biomedical	Weight
Dale et al. 2009	Psychological	Self-efficacy
Davazdah et al. 2009	HbA1c	HbA1c
Sacco et al. 2009	Self-management	Medication adherence
De Greef et al. 2010	Self-management	Physical activity
Osborn et al. 2010	Self-management	Diet adherence
Evans et al. 2010	Psychological	Depression
Hawkins et al. 2010	HbA1c	HbA1c
Wolever et al. 2010	Self-management	Medication adherence
Melkus et al. 2010	HbA1c	HbA1c
Keogh et al. 2011	HbA1c	HbA1c
Welch et al. 2011	HbA1c	HbA1c
Piette et al. 2011	HbA1c	HbA1c
Garcia-Huidobro et al. 2011	HbA1c	HbA1c
Lamers et al. 2011	Psychological	Depressive symptoms
Ell et al. 2011	Psychological	Depressive symptom treatment
De Greef et al. 2011	Self-management	Physical activity
Hamid et al. 2011	HbA1c	HbA1c
Farmer et al. 2012	Self-management	Medication adherence
Hartnamnn et al. 2012	Psychological	Depressive symptoms
Penckofer et al. 2012	Psychological	Depression
Chen et al. 2012	HbA1c	HbA1c
Welschen et al. 2013	Biomedical	Coronary heart disease risk
Jansink et al 2013	HbA1c	HbA1c
Mandel et al. 2013	HbA1c	HbA1c
Plotnikoff et al. 2013	HbA1c	HbA1c
Gois et al. 2014	Psychological	Depressive symptoms
Steed et al. 2014	Psychological	Self-efficacy
Siebolds et al. 2006	HbA1c	Hba1c
Juul et al. 2014	HbA1c	HbA1c
Eakin et al. 2014	Biomedical	Weight loss
Safren et al. 2014	Self-management	Medication adherence
Van Son et al. 2014	Psychological	Stress
Griffin et al. 2014	Self-management	Physical activity
Li et al. 2014	HbA1c	HbA1c

Chlebowy et al. 2015	Self-management	Medication adherence
Petrak et al. 2015	HbA1c	HbA1c
Hermanns et al. 2015	Psychological	Depressive symptoms
Pladevall et al. 2015	HbA1c	HbA1c
Pibernik-Okanović et al. 2015	Psychological	Depressive symptoms
Kim et al. 2015	HbA1c	HbA1c
Browning et al. 2016	HbA1c	HbA1c
Fan et al. 2016	Biomedical	BMI
Wagner et al. 2016	Psychological	Depressive symptoms
Huang et al. 2016	HbA1c	HbA1c
Shayeghian et al. 2016	HbA1c	Hba1c
Kasteleyn et al. 2016	Psychological	Diabetes distress
Chiu et al 2016	Psychological	Diabetes distress
Juul et al. 2016	Biomedical	Weight loss
Jiang et al. 2017	HbA1c	HbA1c
Chee et al. 2017	HbA1c	HbA1c
Balducci et al. 2017	Self-management	Physical Activity
Hermanns et al. 2017	HbA1c	HbA1c
Rees et al. 2017	Psychological	Diabetes distress
Akturan et al. 2017	Psychological	Diabetes Empowerment
Furler et al. 2017	HbA1c	HbA1c
Carrasquillo et al. 2017	HbA1c	HbA1c
Gomes et al. 2017	HbA1c	HbA1c
Egede et al. 2017	Psychological	Depressive symptoms
Munoz-Florez et al. 2017	Self-management	Physical activity
Dobler et al. 2018	Self-management	Physical activity
Momtazi et al. 2018	HbA1c	HbA1c
Ismail et al. 2018	HbA1c	HbA1c
Wroe et al. 2018	Psychological	Depressive symptoms
Chew et al. 2018	Psychological	Diabetes Distress
Chwastiak et al. 2018	HbA1c	HbA1c

Table S4- Frequency of studies with co-morbid depressive symptoms inclusion criteria and HbA1c as a primary outcome

	Primary outcome= HbA1c		
Inclusion criteria=depressive symptoms	**Yes**	**No**	**Total**
Yes	6	10	16
No	27	27	54
Total	33	37	70

Table S5 – Additional inclusion/exclusion criteria information

Reference	Inclusion/exclusion based on mental health or cognitive impairment	Other inclusion criteria	Other exclusion criteria
Whittemore et al. 2004		Female, able to exercise, no advanced diabetes complications, fluent in English, previously participated in diabetes education.	
Williams et al. 2004	Included if systematic depression screening with a 2-item depression screener adapted from the Primary Care Evaluation of Mental Disorders.		
Keeratiyutawong et al. 2006		Only oral diabetes meds, fasting blood glucose >130mg for 2 times or more, read Thai.	Excluded if on insulin therapy, presence of other serious illness or complications relating to diabetes.
Gregg et al. 2007		English-speaking, receiving medical care at low-income community health centre, and referred to diabetes education.	
West et al. 2007		Treated with OADs not insulin, BMI 27-50, able to walk for exercise.	Excluded if pregnant, recent significant weight loss (>10 lbs), or a severe debilitating disease that might interfere with study participation.
Dale et al. 2009	Exclude if severe accompanying disorders (e.g. mentally ill).	Not on insulin, Speak English; no severe accompanying disorders (e.g. mentally ill, severe learning difficulties, severe hearing difficulties).	
Davazdah et al. 2009	Included if presence of depressive symptoms according to DASS scale.		
Sacco et al. 2009	Excluded if evidenced major mental disorder (e.g. schizophrenia) that would potentially interfere with implementation of intervention.	Able to speak and read English, at least one of the following cardiovascular risk factors (low-density lipoprotein =100 mg/dl; high-density lipoprotein=40 mg/dl for men or =45 mg/dl for	

		women; triglycerides =150; cholesterol/high-density lipoprotein ratio =5/1).	
De Greef et al. 2010		No physical activity limitations.	
Osborn et al. 2010		Puerto Rican ethnicity.	
Evans et al. 2010	Borderline personality disorder		
Hawkins et al. 2010			Excluded if unable to pass the Short Portable Mental Status Questionnaire (SPMSQ)
Wolever et al. 2010	Excluded if presence of dementia, Alzheimer, schizophrenia, cognitive impairment.	Have taken OADs for at least 1 year, not on insulin.	
Melkus et al. 2010	Excluded if presence of serious psychiatric disorder.	Black women, not on insulin, BMI<37, not pregnant.	Excluded if diagnosed with a serious medical condition (cancer, AIDS), diabetes related complications.
Keogh et al. 2011			
Welch et al. 2011	Excluded if presence of severe psychiatric disorders or mental retardation, or visual, literacy, or comprehension barriers that would prevent completion of study questionnaires.	Able to speak or write in English.	Excluded if diagnosed with major diabetes complications, or pregnant.
Piette et al. 2011	Included if presence of depressive symptoms according to PHQ (score of 11 or more). Excluded if diagnosed with bipolar disorder or schizophrenia.	Prescribed antihyperglycemic medication.	Excluded if not using antihyperglycemic medication, had been diagnosed with or were in active treatment for another serious illness such as severe heart failure, severe chronic obstructive pulmonary disease, or end-stage renal disease.
Garcia-Huidobro et al. 2011	Excluded if diagnosed with cognitive disorder which limits participation.	Live in household with a significant family member >15yrs.	Excluded if hospitalised during 3m prior HbA1c measurement.
Lamers et al. 2011	Included if presence of depressive symptoms according to MINI (Mild to moderate major depression). Excluded if treatment with		Excluded if on waiting list for nursing home, bedridden, loss of spouse in last 3 months and not being fluent in Dutch.

	antidepressants for depression or present , major psychiatric problems (bipolar depression, schizophrenia, alcohol or substance abuse), current psychosocial/psychiatric treatment, serious cognitive problems.		
Ell et al. 2011	Included if presence of depressive symptoms according to PhQ-9 (one of the two cardinal depression symptoms more than half the days to nearly every day over the last 2 weeks and scored ≥10 on the) PhQ-9. Excluded if present acute suicidal ideation, alcohol abuse, self-reported recent lithium/antipsychotic medication use.		
De Greef et al. 2011		BMI 25-35; pharmaceutically treated for type 2 diabetes; no physical limitations; Speak Dutch.	
Hamid et al. 2011	Included if presence of depressive symptoms according to DASS scale.		
Farmer et al. 2012		Taking OADs (not excluded if taking insulin).	
Hartnamnn et al. 2012	Excluded if presence of psychiatric disorders.		Excluded if presence of albuminuria, non-diabetic kidney disease, alcohol or drug abuse, malignant tumours, heart failure, acute coronary syndrome.
Penckofer et al. 2012	Included if presence of depressive symptoms according to CES-D score (16 more more). Excluded if a history of bipolar depression, or any other psychotic disorder.		Excluded if current alcohol or substance abuse disorders, a diabetes knowledge score <70 % on the Brief Diabetes Knowledge Test (since the program emphasis was not diabetes education); and severe complications of diabetes (blindness, renal failure, or amputation).

Chen et al. 2012	Excluded if presence of psychiatric illness.	Speak Chinese.	Excluded if too ill due to terminal illness or haemodialysis.
Welschen et al. 2013		Able to understand Dutch language, high risk of developing CVD and diabetes complications (HbA1c = 52 mmol/mol (7.0 %) and/or body-mass index = 27.0 kg/m2 and/or smoking).	
Jansink et al 2013		BMI>25.	Exclusion if presence of complex comorbidity and receiving treatment in hospital.
Mandel et al. 2013			Excluded if diagnosed with gestational diabetes, dementia, severe hearing loss.
Plotnikoff et al. 2013		Access to telephone, no English language barrier	
Gois et al. 2014	Included if presence of depressive symptoms according to HADs score (7 or more on depression sub-scale), MADRS (score of 17 or more points), and major depression diagnosis using MINI and DSM-IV. Excluded if history of psychotic disorder or have regular psychoactive medications, active suicidal ideation.		Excluded if presence of severe complications that interfere with self-care activities, other chronic physical disease, alcohol or drug abuse.
Steed et al. 2014		Presence of microalbuminuria as indicated by two or more urinary albumin to creatinine ratios >3.0 mg/mmol or a urinary albumin excretion >30 mg/24h, fluency in spoken English	
Siebolds et al. 2006			
Juul et al. 2014			

Eakin et al. 2014		Physically inactive, BMI 25 or more, not using weight loss medications, without previous or planned bariatric surgery	
Safren et al. 2014	Included if presence of depressive symptoms according to DSM-IV. Excluded if severely depressed (requiring intensive treatment such as hospitalisation). Excluded if untreated major mental illness (e.g., untreated psychosis), bipolar disorder, eating disorder, mental retardation, dementia, or active suicidality or were undergoing current CBT for depression were excluded.		Excluded if unable or unwilling to provide informed consent.
Van Son et al. 2014	Included if Poor emotional well-being (<13 score on WHO-5). Excluded if a recent history of severe psychopathology (i.e., psychosis, risk of suicide attempts), or were already in an (extensive) psychological treatment which started within a period of 6 week before the start of the training.		Excluded if alcohol/drugs abuse; have a severe physical co-morbidity (i.e., severe forms of cancer or heart failure); when they have insufficient reading and comprehension skills of the Dutch language.
Griffin et al. 2014	Excluded if had a psychotic illness.		Excluded if had an illness with a likely prognosis of <1 year; women pregnant.
Li et al. 2014		Education level of at least 6 years.	Excluded if disturbance of consciousness, cognitive disorders or defects in language communication; presence of a severe acute disease or chronic disease (e.g. severe heart failure, lung function failure, tumors).
Chlebowy et al. 2015	Excluded if receiving treatment form a mental health provider.	African American ethnicity; treated by OADs or insulin; English speaking; able to engage in moderate physical activity.	
Petrak et al. 2015	Included if presence of major depression according to DSM-IV. Excluded if suicidal ideations, psychotic symptoms, bipolar	Insulin treated.	Excluded if liver enzyme elevations to exclude severe liver dysfunction.

	disorder, substance abuse or dependence in the past 6 months, psychotherapy in the preceding 3 months, current use of mood stabilizers neuroleptics, antidepressants, or benzodiazepines.		
Hermanns et al. 2015	Included if presence of depressive symptoms CES-D (score of 16 or more). Excluded if presence of major depression, current schizophrenia/psychotic disorder, eating disorder, bipolar disorder, addictive disorder, or personality disorder; current use of antidepressant medication or ongoing psychotherapy.	Sufficient German language skills.	Excluded if bedridden; and under guardianship.
Pladevall et al. 2015		1 or more HbA1c 7% or more ≥1 LDL-C measurement with the last value ≥100 mg/dL, and ≥1 prescription for both an oral diabetes medication and a lipid-lowering medication.	
Pibernik-Okanović et al. 2015	Included if presence of depressive symptoms according to PhQ-2 (1 depressive symptom over past month & need for professional help). Excluded if presence of major depression, or dysthymia, as determined by phone-administered Structured Clinical Interview of DSM-IV, current psychiatric treatment.		Excluded if diagnosed with advanced diabetes complications, medical contraindications for physical exercise.
Kim et al. 2015		Korean American immigrant.	
Browning et al. 2016		Lived in Fengtai district, had health record at participating health services.	
Fan et al. 2016	Excluded if any known psychological or psychiatric disorders, such as major depression or generalize anxiety disorders.		Excluded if severe co-morbidities such as renal failure, hepatic dysfunction, cancer or stroke; uncontrolled complications from diabetes.

Wagner et al. 2016	Excluded for bipolar disorder or thought disorder; or suicide attempt or psychiatric hospitalization in the past 2 years.	Latino or Hispanic, Spanish-speaking.	Excluded for medical instability or intensive medical treatment.
Huang et al. 2016	Included if presence of depressive symptoms according to CES-D (score of 16 or more).	Exclusion= alcohol or drug abuse or dependence, clinically diagnosed neurological illness such as dementia, medical illness, and physical impairments severely influencing the individual's cognitive dysfunction.	
Shayeghian et al. 2016		No change in diabetes medication for 3 months before entering study.	Excluded if hospitalised or diagnosed with diabetes complications.
Kasteleyn et al. 2016		Speak Dutch, no serious illness to prevent participation.	
Chiu et al 2016	Included if occasional distress or minor depressive symptoms. Excluded if on anti-depressant medication, receiving ongoing psychological/psychiatric treatment, diagnosed with psychosis, severe cognitive problem.		Excluded if hearing impairment, lost partner within the past three months.
Juul et al. 2016		Impaired fasting glucose.	
Jiang et al. 2017	Excluded if presence of psychological disorders.	BMI>30.	Excluded if diagnosed with diabetes complications, severe visceral organ disease.
Chee et al. 2017		BMI>23; not treated with insulin, diabetes treatment not changed in last 3 months; nor pregnant; no history of serious diabetes complications	
Balducci et al. 2017		BMI 27-40; physical inactivity; sedentary lifestyle for at least 6m; able to walk 1.6km without assistance	
Hermanns et al. 2017	Excluded if presence of psychiatric disorders, dementia, severe cognitive impairment.	Treated with OADs or 2 years or more, non-intensified insulin treatment, BMI 20-40, read and understand German.	Excluded if severe disease complications or gestational diabetes.

Rees et al. 2017	Included if presence of diabetes distress according to the DDS (score of 2 or more. Excluded if insufficient cognitive ability to engage in study.	Diagnosis of diabetic retinopathy.	Excluded if insufficient English language.
Akturan et al. 2017	Excluded if diagnosed or treated for depression.		
Furler et al. 2017	Excluded if presence of severe mental illness.	Max OAD treatment (2 OADs at max dose).	Excluded if complex debilitating medical condition, such as end stage cancer, or unstable cardiovascular disease.
Carrasquillo et al. 2017		Latino.	
Gomes et al. 2017		Lack of advanced complications, other serious diseases that can prevent participation.	
Egede et al. 2017	Included if presence of depressive symptoms according to DSM-IV criteria for major depressive disorder. Excluded if diagnosis with active psychosis, dementia, suicidal ideation with clear intent, or substance dependence.		
Munoz-Florez et al. 2017		Ability to exercise (low to moderate activity every week).	
Dobler et al. 2018		Speak German; no acute substance-related disorder.	
Momtazi et al. 2018		At least high school diploma, taking oral diabetes medications.	
Ismail et al. 2018	Excluded if presence of severe mental disorders (PhQ-9 >20 if psychotic depression or active suicidal ideation) or receiving psychological treatment elsewhere.		Excluded if diagnosed with a terminal illness and end-stage diabetes complications, BMI>40, non-English.

Wroe et al. 2018	presenting with symptoms consistent with depression or anxiety, or both, as indicated by either PHQ-9 score of 10 or above, or GAD-7 score of 8 or above, and a clinical assessment that indicated a presentation of depression or anxiety.		Excluded if their goals for therapy were not related to an improvement in depression or anxiety.
Chew et al. 2018	Included if presence of diabetes distress according to DDS (score of 3 or more). Excluded if any known psychiatric/psychological disorders that could impair judgement and memory.	Read or understand English or Malay; BP 140/90 mmHG or more; LDL level 2.6 or more.	
Chwastiak et al. 2018	Excluded if presence of cognitive impairment, current suicidality, homicidally.	BP>140/90; read English.	Excluded if grave disability that requires hospitalisation, cardiovascular event in last month, life expectancy less than a year.

Table S6- Frequency of studies with suboptimal glycaemic control as an inclusion criteria and HbA1c as a primary outcome

	Primary outcome= HbA1c		
Inclusion criteria=Suboptimal HbA1c	**Yes**	**No**	**Total**
Yes	8	3	11
No	25	34	59
Total	33	37	70

Table S7- Number of studies and arms included in the network meta-analyses for adults with type 2 diabetes.

Arm	**N**	**%**		**Sample size**
CBT	24	16·44	T	1268
Counselling	46	31·51	T	6105
Usual care	46	31·51	C	5954
Attention control	18	12·33	C	1297
Self-help materials	4	2·74	C	792
IPT	1	0·68	T	11
Diabetes education	1	0·68	C	46
Waiting list control	6	4·11	C	229
Total	146	100		15702

T=arm was defined as treatment arm and C= arm was defined as control group in original study.
IPT=interpersonal therapy.

Table S8- Direct and indirect treatment effects (where indirect treatment effects were available) and the difference between them for adults with type 2 diabetes, including significance test for difference.

Comparison		Direct		Indirect		Difference		
		SMD	SE	SMD	SE	SMD	SE	p
Usual care	Attention control	-0·02	0·281	-0·032	0·083	0·012	0·293	0·966
Usual care	Self-help materials	-0·091	0·176	-0·412	0·171	0·321	0·246	0·192
CBT	Usual care	0·231	0·081	0·088	0·136	0·144	0·158	0·364
CBT	Attention control	0·035	0·126	0·275	0·118	-0·241	0·173	0·164
CBT	Self-help materials	-0·117	0·288	-0·048	0·153	-0·068	0·326	0·834
CBT	Waiting list control	0·352	0·209	0·266	0·207	0·086	0·295	0·770
Counselling	Usual care	0·188	0·053	0·259	0·151	-0·071	0·16	0·659
Counselling	Attention control	0·231	0·079	-0·044	0·141	0·274	0·162	0·091
Counselling	Self-help materials	-0·192	0·151	0·174	0·201	-0·366	0·252	0·146
Counselling	Waiting list control	0·274	0·191	0·36	0·224	-0·086	0·295	0·770
Attention control	Self-help materials	0·102	0·285	-0·317	0·15	0·419	0·322	0·193

Table S9- Summary of treatment effects compared with usual care assuming common heterogeneity estimate for all treatment design comparisons for adults with type 2 diabetes.

Treatment	b	95% C.I.	SE	z	p
Usual care	0				
CBT	-0·194	-0·33 to -0·057	0·069	-2·79	0·005
Counselling	-0·196	-0·292 to -0·099	0·049	-3·97	<0·001
Attention control	-0·031	-0·185 to 0·124	0·079	-0·39	0·698
Self-help material	-0·257	-0·499 to -0·015	0·123	-2·08	0·037
Waiting list control	0·114	-0·174 to 0·402	0·147	0·78	0·437

Table S10- Summary of pairwise comparisons of all treatment assuming common heterogeneity estimate for all treatment design comparisons for adults with T2DM. SMD=SMD: Standardised mean difference

Treatment comparison		SMD	(95% C.I>)	SE	z	p
Usual care	CBT	-0.264	(-0.41 to -0.117)	0.075	-3.520	**<0.001**
Usual care	Counselling	-0.222	(-0.313 to -0.13)	0.047	-4.740	**<0.001**
Usual care	Attention control	-0.038	(-0.192 to 0.117)	0.079	-0.480	0.635
Usual care	Self-help materials	-0.243	(-0.479 to -0.007)	0.120	-2.020	**0.044**
Usual care	IPT	0.059	(-0.222 to 0.341)	0.144	0.410	0.679
Usual care	Structured diabetes	-0.160	(-0.475 to 0.154)	0.160	-1.000	0.318
Counselling	CBT	0.042	(-0.123 to 0.208)	0.084	0.500	0.616
Attention control	CBT	0.226	(0.034 to 0.418)	0.098	2.310	**0.021**
Self-help materials	CBT	0.021	(-0.251 to 0.293)	0.139	0.150	0.880
IPT	CBT	0.323	(0.009 to 0.638)	0.160	2.010	**0.044**
Structured diabetes	CBT	0.104	(-0.239 to 0.447)	0.175	0.590	0.553
Attention control	Counselling	0.184	(0.044 to 0.324)	0.071	2.580	**0.010**
Self-help materials	Counselling	-0.021	(-0.252 to 0.21)	0.118	-0.180	0.857
IPT	Counselling	0.281	(-0.01 to 0.572)	0.149	1.890	0.059
Structured diabetes	Counselling	0.061	(-0.239 to 0.362)	0.153	0.400	0.689
Self-help material	Attention control	-0.205	(-0.459 to 0.049)	0.129	-1.590	0.113
IPT	Attention control	0.097	(-0.207 to 0.401)	0.155	0.620	0.532
Structured diabetes	Attention control	-0.123	(-0.454 to 0.209)	0.169	-0.730	0.468
IPT	Self-help material	0.302	(-0.061 to 0.665)	0.185	1.630	0.103
Structured diabetes	Self-help material	0.083	(-0.296 to 0.461)	0.193	0.430	0.669
Structured diabetes	IPT	-0.219	(-0.637 to 0.199)	0.213	-1.030	0.305

Table S11- Probability to be the best treatment, mean rank and surface under the cumulative curve (SUCRA) for adults with type 2 diabetes derived from ranking probabilities.

Rank	Usual care	CBT	Counselling	Attention control	Self-help materials	Waiting list control
Best	0	22.4	18.8	0.1	58.1	0.6
MEAN RANK	4.9	2.2	2.2	4.5	1.8	5.5
SUCRA	0.2	0.8	0.8	0.3	0.8	0.1

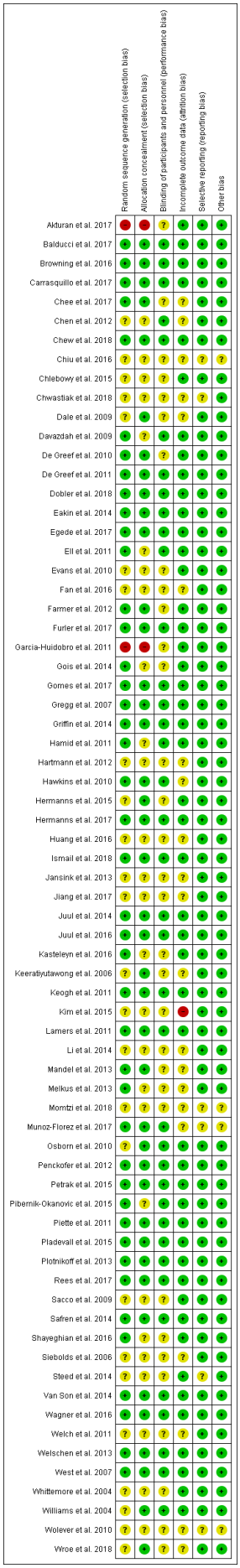


Figure S1- Risk of bias within RCTs of psychological interventions for adults with Type 2 diabetes.

Figure S2- Risk of bias domain assessment across psychological intervention RCTs for adults with Type 2 diabetes.

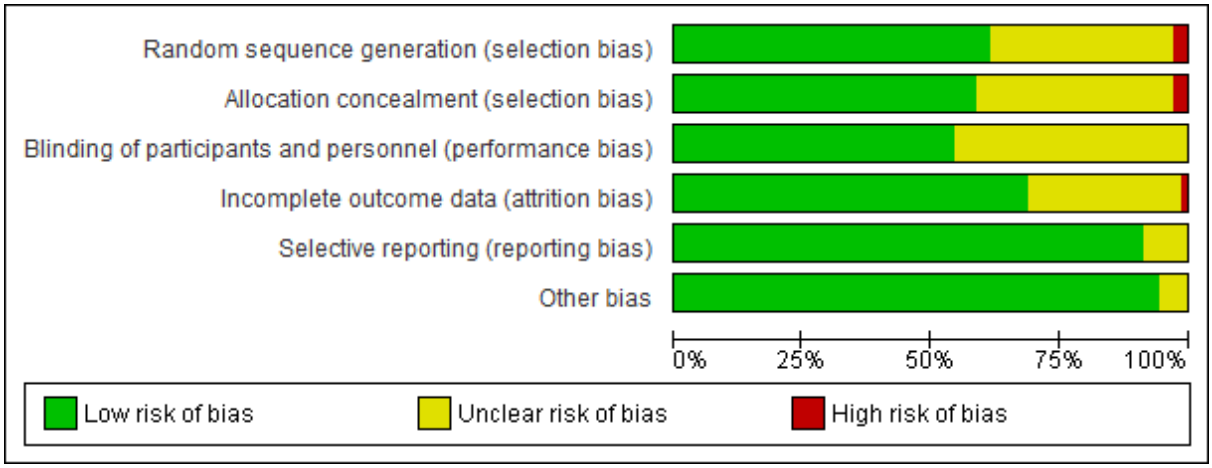
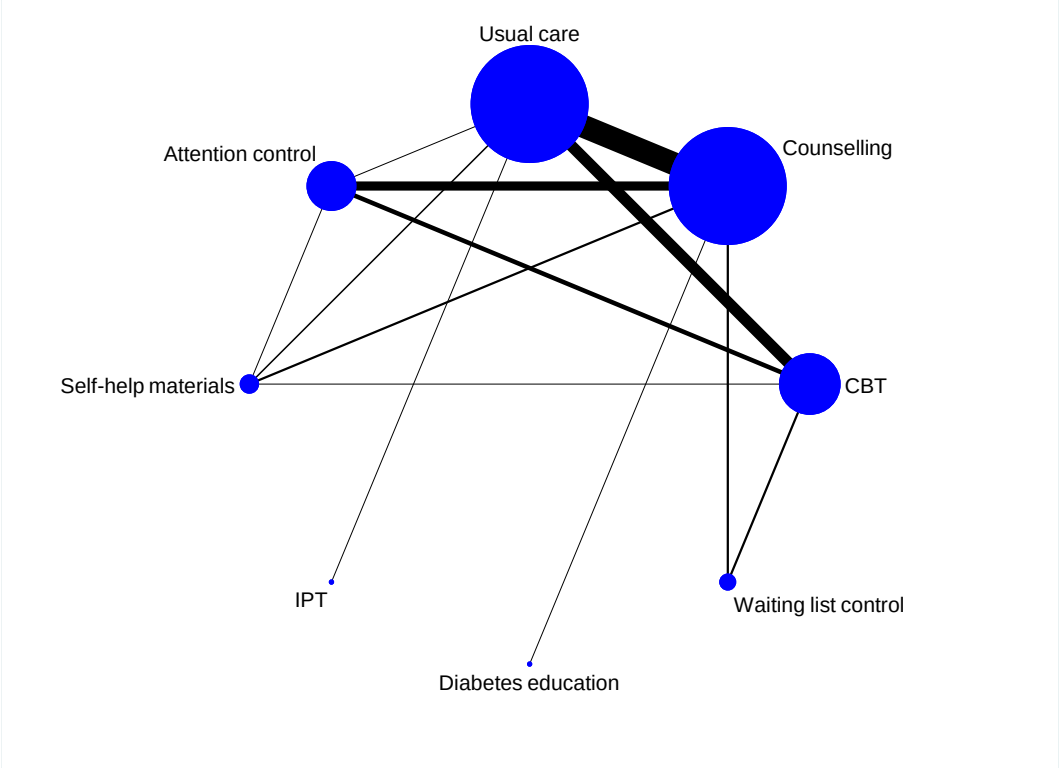


Figure S3- Network plots for reduce number of studies (N=143). Network plots of direct comparisons for the network meta-analysis for adults with type 2 diabetes.



The width of the lines is proportional to the number of trials comparing each pair of treatments and the size of each node is proportional to the number of studies testing the specific treatment. It shows roughly how much information is available for each treatment and for each treatment comparison. IPT=interpersonal therapy, CBT=cognitive behavioural therapy.

Appendix 2.2: PRISMA checklist for study 1

Section/topic	#	Checklist item	Section reported in this thesis
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	Chapter 2 heading
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	Appendix 2.1
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	2.2
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	2.2
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	2.3.1
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	2.3.2
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	2.3.3
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	2.3.4
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	2.3.5

Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	2.3.6
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	2.3.7
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	2.3.8
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	2.3.9
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	2.3.9

Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	2.3.10
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	2.3.11
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	2.4.1
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	2.4.2
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	2.4.3
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	2.4.4
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	2.4.4
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	2.4.5
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	2.4.6

DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	2.5.1
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	2.5.2
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	2.5.3
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	Statement of contribution

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

Appendix 2.3: MEDLINE search strategy

1. exp Diabetes Mellitus/
2. diabet$.ab,ti.
3. (DKA or IDDM).mp. or DMI.ab,ti. [mp=title, original title, abstract, name of substance word, subject heading word]
4. (MODY or DM2 or NIDDM).mp. or IIDM.ti,ab. [mp=title, original title, abstract, name of substance word, subject heading word]
5. insulin$ secret$ dysfunc$.ti,ab.
6. insulin$ resist$.ti,ab.
7. ((impaired glucose tolerance or glucose intoleran$ or insulin$ resist$) and (DM or DM2)).ti,ab.
8. insulin$ depend$.mp. or insulin?depend$.ti,ab. [mp=title, original title, abstract, name of substance word, subject heading word]
9. (non insulin$ depend$ or nonisulin$ depend$ or nonisulin?depend).mp. or non insulin?depend$.ti,ab. [mp=title, original title, abstract, name of substance word, subject heading word]
10. (("typ$ 1" or typ$ I) adj6 DM).ti,ab.
11. (("typ$ 2" or typ$ II) adj6 DM).ti,ab.
12. ((juvenil$ or child$ or keto$ or labil$ or brittl$ or earl$ onset) adj6 (DM or DM1)).ti,ab.
13. ((keto$ prone or autoimmun$ or auto immun$ or sudden onset) adj6 (DM or DM1)).ti,ab.
14. ((keto$ resist$ or nonketo$ or non keto$ or adult$ onset or matur$ onset or late$ onset or slow onset or stabl$) adj6 (DM or DM2)).ti,ab.
15. exp Insulin Resistance/
16. (insulin$ defic$ adj6 (absolut$ or relativ$)).ti,ab.
17. metabolic$ syndrom$.ti,ab.
18. (syndrom$ X not (fragil$ X or X linked)).ti,ab.
19. (plurimetabolic$ syndrom$ or pluri metabolic$ syndrom$).ti,ab.
20. or/1-19
21. exp Psychotherapy/
22. exp Counseling/
23. exp Mood disorders/
24. exp Depression/
25. psycho$.mp
26. counsel$.mp
27. depression.mp
28. depressive.mp
29. (interpersonal adj5 therap$).mp
30. art therap$.mp
31. aversion therap$.mp
32. balint.mp
33. behavio?r adj5 (intervention or therap* or modific*)
34. cognitive adj5 (therap* or intervention or program* or train* or theory)
35. (family adj3 (intervention or treatment or counsel* or therap*)
36. colo?r therap$.mp.
37. crisis intervention.mp
38. dance therap$.mp
39. gestalt therap$.mp
40. music therap$.mp

41. milieu therap$.mp
42. (assert$ adj5 training).mp
43. Narrative therap$.mp.
44. nondirective therap$.mp
45. (problem solving adj5 therap$).mp
46. (self control adj5 therap$).mp
47. person cent$.mp
48. client cent$.mp
49. psychodrama$.mp
50. paradoxical technique$.mp
51. play therap$.mp
52. rational emotive.mp
53. reality therap$.mp
54. role play$.mp
55. (relax$ adj5 training).mp
56. sociotherap$.mp
57. socioenvironmental.mp
58. supportive therap$.mp
59. transactional.mp
60. acceptance adj2 (commitment therap*)
61. coping skills training.mp.
62. exp Mindfulness/
63. motivation* adj2 (interview* or therap*)
64. multisystemic therapy
65. or/21-64
66. Randomized Controlled Trials as Topic/
67. randomized controlled trial/
68. Random Allocation/
69. Double Blind Method/
70. Single Blind Method/
71. clinical trial/
72. clinical trial, phase i.pt
73. clinical trial, phase ii.pt
74. clinical trial, phase iii.pt
75. clinical trial, phase iv.pt
76. controlled clinical trial.pt
77. randomized controlled trial.pt
78. multicenter study.pt
79. clinical trial.pt
80. exp Clinical Trials as topic/
81. (clinical adj25 trial$).tw
82. ((singl$ or doubl$ or treb$ or tripl$) adj25 (blind$3 or mask$3)).tw
83. PLACEBOS/
84. placebo$.tw
85. randomly allocated.tw
86. (allocated adj2 random$).tw
87. Or/66-86
88. case report.tw
89. letter/
90. historical article/
91. Or/ 88-90

92. 87 NOT 91
93. 20 AND 65 AND 92
94. limit 88 to yr="2003 -Current"

Appendix 3.1: COREQ Checklist for study 2

COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported in section of this thesis
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	3.3.3
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	3.3.3 and reflexivity statement
Occupation	3	What was their occupation at the time of the study?	3.3.3 and reflexivity statement
Gender	4	Was the researcher male or female?	3.3.3
Experience and training	5	What experience or training did the researcher have?	3.3.3
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	3.3.3
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	3.3.3
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	Reflexivity statement
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	3.3.4
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	3.3.1
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	3.3.3
Sample size	12	How many participants were in the study?	3.4
Non-participation	13	How many people refused to participate or dropped out? Reasons?	3.4
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	3.3.3
Presence of nonparticipants	15	Was anyone else present besides the participants and researchers?	3.3.3
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	3.4
Topic	**Item No.**	**Guide Questions/Description**	**Reported on Page No.**
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	3.3.3

Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	3.3.3
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	3.3.4
Field notes	20	Were field notes made during and/or after the interview or focus group?	3.3.4
Duration	21	What was the duration of the inter views or focus group?	3.4
Data saturation	22	Was data saturation discussed?	3.3.3 (information power)
Transcripts returned	23	Were transcripts returned to participants for comment and/or correction?	3.5.4
Domain 3: analysis and findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	3.3.4
Description of the coding tree	25	Did authors provide a description of the coding tree?	3.4 (figure 1)
Derivation of themes	26	Were themes identified in advance or derived from the data?	3.3.4
Software	27	What software, if applicable, was used to manage the data?	3.3.4
Participant checking	28	Did participants provide feedback on the findings?	3.5.4
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	3.4
Data and findings consistent	30	Was there consistency between the data presented and the findings?	3.5.4
Clarity of major themes	31	Were major themes clearly presented in the findings?	3.4
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	3.4

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

Appendix 3.2: Information sheet for study 2

Patient information sheet

Title of project: Patient views and experiences of starting insulin therapy.

You are being invited to participate in a study which involves interviewing type 2 diabetic patients who have started or are due to start on insulin. This study is funded by the National Institute for Health Research (NIHR). Before you decide whether to take part in this study it is important that you understand why the research is being conducted and what is involved. Please take time to read the following information and feel free to ask if there is anything that is not clear or if you would like more information.

1. What is the purpose of this study?

This study is part of a research project in the department of Psychological Medicine at King's College London. The purpose of this study is to determine patient views on the barriers to insulin self-management, views on diabetes education courses (if you have attended any) and suggestions for additional support to aid self-management in Type 2 diabetes. This will be used to develop a new group intervention to help people start insulin with Type 2 diabetes.

2. Do I have to take part?

No. It is entirely your decision as to whether you take part in this study. If you decide to take part, you will be asked to complete a consent form. However, you are still free to withdraw at any time during the study period without giving a reason.

3. What will happen to me if I take part?

If you decide to take part in the study, please fill out the consent form (attached). You will then be invited to an interview which will take place at your local diabetes clinic or GP surgery in Lambeth, at an agreed time/date of your convenience. The duration of the interview will be around 30 minutes. The interviewer will be a diabetes nurse or researcher. The interviewer will ask your views on barriers to insulin self-management, current diabetes education courses and suggestions for additional support to aid self-management in Type 2 diabetes. Interviews will be recorded.

4. What are the possible disadvantages or risks of taking part?

We do not foresee any disadvantages of participating in this study. You do not have to answer any questions if you do not wish to.

5. What are the possible advantages of taking part?

You will have opportunity to share your thoughts of diabetes and insulin initiation in depth. The results from these interviews will help in the development of an intervention to improve health outcomes following insulin initiation.

6. Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practise and all information about you will be handled in confidence. We will also take measures to anonymise the data you give us. You will be given this information sheet and a signed consent form to keep, if you wish.

Contact details (email, telephone numbers, and/or addresses) of participants will be kept in a file, in a locked filing cabinet in a locked office at a King's College London University campus. Audiotapes of interviews will be also kept in a locked filing cabinet. Typed transcripts of interview recordings will be stored on a University password-protected computer in a locked office at the University. Password-protected laptops may be used to transcribe interviews, these will be kept in the locked office when not in use. Only the research team, chief investigator and PhD student, will have access to password protected computers/laptops which contain data for this research, in addition to locked filing cabinets. The clinical team of the patient will have access to NHS computers with patient medical data, the research team will only have access to this information with consent of the patient.

King's College London policy advises that data which is funded and is published can be retained for 7 years to cover contractual liability. After this, data will be disposed securely. For paper records, they will be shredded within the King's College London office or disposed via the College confidential waste service. For disposal of electronic records, information held on local databases (i.e. participant contact details) will be deleted once it ceases to be relevant (i.e. once the project is completed, or sooner if the information has no further use). Once retention period has expired, research data in electronic form will be erased from the computer hard drive.

7. Who has reviewed the study?

The research proposal has been reviewed by staff in the Academic Department of Diabetes at King's College London and by the local Research Ethics Committee at King's College Hospital NHS Foundation Trust.

Further information and contact details

If you have any further questions or wish to know more information please do not hesitate to contact the researchers on:

kirsty.1.winkley@kcl.ac.uk, 02078485664 (Chief Investigator)

rebecca.j.upsher@kcl.ac.uk, 02078485666 (PhD student)

If you would like to seek assistance if you have any concerns about any aspect of the study, please contact the Patient Advice and Liaison Service (PALS):

Telephone: 020 3299 3625 or 020 3299 360,

or write to PALS, King's College Hospital, Denmark Hill, London SE5 9RS

If you have any questions concerning your rights as a study participant you may wish to read the following leaflet: Getting Involved in Research: A guide for consumers, available at: http://www.invo.org.uk/pdfs/guide_for_consumers.pdf or contact the Consumers in NHS Research Support Unit, Tel: 01962 872247.

Thank you very much for taking the time to read this information.

Appendix 3.3: Consent form for study 2

KING'S COLLEGE LONDON PARTICIPANT CONSENT FORM

Title of Project: Patient views and experiences of starting insulin therapy
Name of Researcher:

Please check the box if you agree with the statements:

1. I confirm that I have read the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers. ☐
4. I am willing and able to attend an interview at my local diabetes clinic/GP surgery. ☐
5. I am willing for my interview to be recorded ☐
6. I agree to take part in the above study. ☐
7. I agree to my General Practitioner being informed of my participation in the study. ☐

Name of Participant	Date	Signature
Name of Researcher	Date	Signature

Appendix 4.1: General Data Protection Regulation Health Research Authority information letter for SOUL-D follow-up study

The South London Diabetes (SOUL-D) study long-term follow-up study (IRAS ID 223971)

You may remember participating in the South London Diabetes (SOUL-D) study about 6-8 years ago. Thank you for your participation in this study. You consented to your medical records to be accessed by the research team for a period of up to 20 years. Here is some information on how we will be using your personal data, and what rights are under the law. Please contact us on with details below if you have any questions regarding this information.

King's College Hospital is the sponsor for this study based in United Kingdom. We will be using information from you and/or your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. King's College Hospital will keep identifiable information about you for 10 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information by contacting Lisa Kuriakose (lisa.kuriakose@kcl.ac.uk).

King's College London will use your name, NHS number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from King's College Hospital and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Your GP surgery will pass these details to King's College London along with the information collected from you and/or your medical records. The only people in King's College London who will have access to information that identifies you will be people who need to contact you about future opportunities to participate in research or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

King's College London will keep identifiable information about you from this study for 10 years after the study has finished.

King's College London will collect information about you for this SOUL-D research study from medical records. This information will include your name/ NHS number/ contact details/ add other identifiers and health information, which is regarded as a special category of information. We will use this information to determine whether your information obtained at the time of your type 2 diabetes diagnosis is associated with subsequent diagnoses, treatments, mortality, blood sugar control, complications and occupational decline.

Your information could be used for research in any aspect of health or care, and could be combined with information about you from other sources held by researchers, the NHS or government.

Where this information could identify you, the information will be held securely with strict arrangements about who can access the information. The information will only be used for the purpose of health and care research, or to contact you about future opportunities to participate in research. It will not be used to make decisions about future services available to you, such as insurance.

Where there is a risk that you can be identified your data will only be used in research that has been independently reviewed by an ethics committee.

Further information and contact details

If you would like further information about this study please contact:

Lisa Kuriakose

Research Assistant

Tel.: 020 7848 5759

Email: lisa.kuriakose@kcl.ac.uk

If you have any questions or complaints at any stage, you can contact the Patient Advice and Liaison Service at King's College Hospital on 020 3299 3601.

Kind regards,

Professor Khalida Ismail

Chief Investigator

Appendix 5.1: Definition of intervention functions

The following definitions can be found in the Behaviour Change Wheel guide (Michie et al., 2014). Examples are in relation to improving insulin self-management.

Met APEASE criteria for DIME:

- **Training:** Communicating skills e.g. training in insulin injection technique.
- **Education:** Providing information to increase knowledge e.g. providing information to promote insulin therapy for type 2 diabetes.
- **Environmental restructuring:** Altering the physical or the social environment e.g. ensuring insulin education location is accessible to attendees.
- **Enablement:** Increase capability (not by education or training) or opportunity (not via environmental restructuring) by increasing means or reducing barriers e.g. behavioural support for initiating insulin.
- **Modelling:** A demonstration of a behaviour for people to copy e.g. diabetes nurse demonstrates injecting insulin.
- **Persuasion:** Changing attitudes or behaviour by communicating information which stimulates positive or negative feelings e.g. Using imagery of fatty liver to motivate weight loss.

Did not meet APEASE criteria for DIME:

- **Incentivisation:** Providing potential prize by engaging in a behaviour e.g. prize draw
- **Coercion:** Suggestion of potential punishment e.g. increase cost of cigarettes
- **Restriction:** Reduce opportunity to participate in a behaviour by using rules e.g. prohibit sales of energy drinks to under 16s

Appendix 5.2: Definition of policy categories

The following definitions can be found in the Behaviour Change Wheel (Michie et al., 2014).

Met APEASE criteria for DIME:

- **Communication/marketing:** E.g. leaflets, electronic media, telephone marketing or broadcast.
- **Service provision:** Service delivery e.g. support services
- **Environmental/social planning:** Design or control of the physical or social environment e.g. town planning

Did not meet APEASE criteria for DIME:

- **Guidelines:** Recommendations for practice e.g. treatment protocol
- **Fiscal measures:** Use tax to increase or reduce cost e.g. sugar tax
- **Regulation:** Rules for practice e.g. agreements on advertisements
- **Legislation:** Creating or amending laws e.g. banning smoking in indoor public spaces

Appendix 5.3: Definition of APEASE criteria

The following definitions can be found in the Behaviour Change Wheel guide (Michie et al., 2014).

Below are the definitions of the APEASE criterion:

- **Affordability:** The intervention can be delivered within an acceptable budget and can be financially accessed by people it is relevant to.
- **Practicability:** The intervention can be delivered as intended in the context it was created for e.g. in practice not just in research where staff are specially trained.
- **Effectiveness and cost-effectiveness:** Effectiveness relates to effect size of the intervention when delivered in a controlled trial (intervention vs control group). Cost-effectiveness relates to the ratio of effect to the cost.
- **Acceptability:** The judgement of the intervention according to stakeholders e.g. patients, healthcare professionals etc.
- **Side-effects/safety:** Intervention design needs to consider safety aspects and any potentially harmful side effects.
- **Equity:** A consideration of whether the intervention reduces or increases the disparities between different sectors of society in terms of wellbeing or health.

Appendix 6.1: TIDieR checklist for study 4

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Item number	Item	Where located ** Section of this thesis
	BRIEF NAME	
1.	Provide the name or a phrase that describes the intervention.	6.2
	WHY	
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	6.3
	WHAT	
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	6.4.1
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	6.4.2
	WHO PROVIDED	
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	6.5
	HOW	
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	6.6
	WHERE	
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	6.7

	WHEN and HOW MUCH	
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	6.8
	TAILORING	
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	6.9
	MODIFICATIONS	
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	6.9
	HOW WELL	
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	6.10
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	N/A

Appendix 6.2: DIME facilitator notes

Appendix redacted. Please contact rebecca.j.upsher@kcl.ac.uk for more information.

Appendix 6.3: DIME workbooks

Appendix redacted. Please contact rebecca.j.upsher@kcl.ac.uk for more information.

Appendix 6.4: DIME printed materials

Appendix redacted. Please contact rebecca.j.upsher@kcl.ac.uk for more information.

Appendix 6.5: Information sheet for study 4

Patient information sheet

Title of project: Testing of a newly developed group intervention to help people with type 2 diabetes start insulin.

You are being invited to participate in a study which will involve testing a new intervention to help type 2 diabetic patients start insulin. This study is funded by the National Institute for Health Research (NIHR). Before you decide whether to take part in this study it is important that you understand why the research is being conducted and what is involved. Please take time to read the following information and feel free to ask if there is anything that is not clear or if you would like more information.

1. What is the purpose of this study?

This study is part of a research project in the department of Psychological Medicine at King's College London. The purpose of this study is to test a newly developed group intervention to help people with type 2 diabetes start insulin.

2. Do I have to take part?

No. It is entirely your decision as to whether you take part in this study. If you do decide to take part, you will be asked to complete a consent form. However, you are still free to withdraw at any time during the study period without giving a reason.

3. What will happen to me if I take part?

If you decide to take part in the study, please fill out the consent form (attached). You will then be invited to a group (6-10 people) intervention with others who have just started insulin, this will last around 1.5 hours at a community venue in Lambeth. Following the group session you will be asked to provide feedback via interview on the intervention, for example, views on content, appropriateness for patients starting insulin as well as suggestions for future development. Interviews will be recorded. The interview will take place at your local GP surgery.

4. What are the possible disadvantages or risks of taking part?

We do not foresee any disadvantages of participating in this study. You do not have to answer any questions you do not desire.

5. What are the possible advantages of taking part?

You will receive a newly developed, evidenced-based group intervention which is not currently available. This could result in improved outcomes following insulin initiation such as reduced hyperglycaemia.

6. Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practise and all information about you will be handled in confidence. We will also take measures to anonymise the data you give us. You will be given this information sheet and a signed consent form to keep, if you wish.

Contact details (email, telephone numbers, and/or addresses) of participants will be kept in a file, in a locked filing cabinet in a locked office at a King's College London University campus. Audiotapes of interviews will be also kept in a locked filing

cabinet. Typed transcripts of interview recordings will be stored on a University password-protected computer in a locked office at the University. Password-protected laptops may be used to transcribe interviews, these will be kept in the locked office when not in use. Only the research team, chief investigator and PhD student, will have access to password protected computers/laptops which contain data for this research, in addition to locked filing cabinets. The clinical team of the patient will have access to NHS computers with patient medical data, the research team will only have access to this information with consent of the patient.

King's College London policy advises that data which is funded and is published can be retained for 7 years to cover contractual liability. After this, data will be disposed securely. For paper records, they will be shredded within the King's College London office or disposed via the College confidential waste service. For disposal of electronic records, information held on local databases (i.e. participant contact details) will be deleted once it ceases to be relevant (i.e. once the project is completed, or sooner if the information has no further use). Once retention period has expired, research data in electronic form will be erased from the computer hard drive.

7. Who has reviewed the study?

The research proposal has been reviewed by staff in the Academic Department of Diabetes at King's College London and by the local Research Ethics Committee at King's College Hospital NHS Foundation Trust.

Further information and contact details

If you have any further questions or wish to know more information please do not hesitate to contact the researchers on:

kirsty.1.winkley@kcl.ac.uk, 02078485664 (Chief Investigator)

rebecca.j.upsher@kcl.ac.uk, 02078485666 (PhD student)

If you would like to seek assistance if you have any concerns about any aspect of the study, please contact the Patient Advice and Liaison Service (PALS):

Telephone: 020 3299 3625 or 020 3299 360,

or write to PALS, King's College Hospital, Denmark Hill, London SE5 9RS

If you have any questions concerning your rights as a study participant you may wish to read the following leaflet: Getting Involved in Research: A guide for consumers, available at: http://www.invo.org.uk/pdfs/guide_for_consumers.pdf or contact the Consumers in NHS Research Support Unit, Tel: 01962 872247.

Thank you very much for taking the time to read this information.

Appendix 6.6: Consent form for study 4

KING'S COLLEGE LONDON PARTICIPANT CONSENT FORM

Title of Project: Testing of a newly developed group intervention to help people with type 2 diabetes start insulin.
Name of Researcher:

Please check the box if you agree with the statements:

1. I confirm that I have read the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers. ☐
4. I am willing and able to attend an interview at my local diabetes clinic/GP surgery. ☐
5. I am willing to have my interview recorded ☐
6. I agree to take part in the above study. ☐
7. I agree to my General Practitioner being informed of my participation in the study. ☐

Name of Participant	Date	Signature
Name of Researcher	Date	Signature

Appendix 7.1: COREQ Checklist for study 5

COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported in section of this thesis
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	7.3.2
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	7.3.2
Occupation	3	What was their occupation at the time of the study?	7.3.2
Gender	4	Was the researcher male or female?	7.3.2
Experience and training	5	What experience or training did the researcher have?	7.3.2
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	7.2
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	7.3.2
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	7.3.2
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	7.3.3
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	7.3.1
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	7.3.2
Sample size	12	How many participants were in the study?	7.4.1
Non-participation	13	How many people refused to participate or dropped out? Reasons?	7.2
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	7.3.2
Presence of nonparticipants	15	Was anyone else present besides the participants and researchers?	7.3.2
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	7.4.1

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	7.3.2; appendix 7.2
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	7.3.2
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	7.3.2
Field notes	20	Were field notes made during and/or after the inter view or focus group?	7.3.2
Duration	21	What was the duration of the inter views or focus group?	7.4.2
Data saturation	22	Was data saturation discussed?	7.5.2
Transcripts returned	23	Were transcripts returned to participants for comment and/or correction?	7.5.2
Domain 3: analysis and findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	7.3.3
Description of the coding tree	25	Did authors provide a description of the coding tree?	7.4.2; figure 7.1
Derivation of themes	26	Were themes identified in advance or derived from the data?	7.3.3
Software	27	What software, if applicable, was used to manage the data?	7.3.3
Participant checking	28	Did participants provide feedback on the findings?	7.5.2
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	7.4.2
Data and findings consistent	30	Was there consistency between the data presented and the findings?	7.4.2
Clarity of major themes	31	Were major themes clearly presented in the findings?	7.4.2
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	7.4.2

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

Appendix 7.2: Interview schedule for DIME pilot exit interviews for study 5

Warm up question

Tell me a little about the insulin you are taking….

Main questions

1. Why did you choose to attend the insulin education group?
    - Prompts:
        - What did you hope to achieve by attending the group?
        - Was there anything that worried you about attending the group sessions?
2. In what ways did the insulin education groups meet your expectations/needs?
    - Prompts:
        - Did the course cover all the things you wanted to learn about?
        - What did you think about having group sessions?
3. In what ways did the insulin education group fail to meet your expectations/needs?
    - Prompts:
        - Was there anything else you wanted the course to cover?
        - What else would you have liked?
4. In what ways do you think the knowledge you have gained from the group has benefited you?
    - Prompts:
        - Has your management of diabetes changed following the group sessions? How so?
        - Can you tell me about any changes in the way you feel about your diabetes as a result of attending these sessions?
        - What are the most important benefits that have resulted from the group?
        - What helped you learn?
5. How do you feel about the resources which were given to you to take home?
    - Prompts:
        - Did you read any of it after the session?
        - What would be the most useful in terms of materials to take home with you?
6. How did you feel about the activities in the group sessions?
    - Prompts:
        - Which ones did you enjoy/ not enjoy?
        - How could the activities be improved?
7. How would you rate the overall success of the insulin education group from a scale of 1 to 10 where 1 is a complete failure and 10 is a total success?

- Prompts:
    - What would help improve this rating?

8. What are your views about the number of sessions you had for the insulin group?
    - Prompts:
        - Too little/too many?
        - Preferred a whole day session instead or longer 2 sessions?
        - What are your views about the length of sessions?
9. Were there any barriers to you attending the sessions?
    - Prompts:
        - What would have made it easier to attend?
10. What do you think about the way the sessions were structured?
    - Prompts:
        - Was the content understandable/easy to follow?
        - What do you think about the way the nurse talked to you during the appoints/style of talking?
        - Were the topics ordered in a way that made sense to you?
11. Can you think of anything the insulin groups could differently to support ongoing self-management of insulin for people with type 2 diabetes?
    - Prompts:
        - Any recommendations for future groups?

Final comments

12. Is there anything else at all you would like to say that we haven't covered already?